Comparison of American Diabetes Association (ADA) and World Health Organization (WHO) criteria in the screening and diagnosis of gestational diabetes mellitus in South Indian population

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Received: 20th August, 2018 **Accepted:** 2nd February, 2019

Abstract

Introduction: Diagnosis of gestational diabetes mellitus (GDM) depends on the guidelines used.This study was carried out to compare ADA criteria`s diagnostic accuracy and validity in diagnosing GDM and its complication considering WHO criteria as gold standard.

Materials and Methods: Patients who underwent 75 gram Oral Glucose Tolerance test (OGTT) for GDM screening were included in the study. The retrospective data included 559 subjects, whereas prospective design included 620 mothers who were followed for maternal and foetal outcomes.

Results: Prevalence of GDM was 11.2%. ADA and WHO criteria were found to have an agreement of 0.69. Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value of ADA was 69.81%, 97.58%, 74.0% and 97.03% respectively. WHO second hour identified all cases of GDM. Mothers diagnosed to have GDM by either criterion were older, had increased body mass index. The difference in the prevalence of preeclampsia (p=0.02), macrosomia (p=0.001) and increased birth weight (p=0.003) were found to be significant in WHO criteria alone. Maternal and foetal outcomes didn't show any significant difference.

Conclusion: This study concludes that the diagnostic accuracy of ADA was comparable with WHO criteria. WHO criteria predicated the complications of GDM at a higher rate than ADA criteria. WHO second-hour criterion alone may be used as a screening test to diagnose GDM.

Keywords: American diabetes association, Foetal outcomes, Gestational diabetes mellitus, Maternal outcomes, World health organization.

Introduction

"Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance with recognition or onset during pregnancy, irrespective of the treatment with diet or insulin".[1] There is increased risk of perinatal morbidity and mortality and greater frequency of long-term complications that would justify its proper identification and its management.[2,3] The status of maternal glycaemia continuously increased maternal, foetal, and neonatal adverse outcomes like increased primary caesarean section rate, instrumental delivery, preeclampsia, macrosomia, foetal hyperinsulinaemia, new born adiposity and shoulder dystocia.[4]

In developing countries like India, the prevalence of GDM is increasing due to increasing urbanisation, decreased physical activity, dietary pattern changes and obesity. It differs from 3.8 to 21%.[5] The prevalence is influenced by the method used for diagnosis and the geographical area studied.[6] The prevalence is more in urban areas when compared with rural areas which may be explained by increased maternal age, sedentary lifestyle and obesity.[7]

Various guidelines are available for GDM screening and diagnosis. As Indian women are at increased risk, universal screening is of paramount importance.[3]American Diabetes Association recommends screening at early weeks for women with increased risk for GDM. Ideal time for screening is between 24 and 28 weeks. Oral glucose tolerance test (OGTT) is done after 8 hrs of fasting. Three samples are collected.[8] According to WHO criteria, only two samples are collected following 75 gm glucose load and GDM is diagnosed if one value exceeds th e cut-off in both the criteria (Table 1).[9]

The prevalence of GDM varies depending upon the criteria used. The number of samples collected in OGTT procedure for different criteria plays an important role in the implication of these criteria as they influence the cost involved in the Diagnosis was made if any one criteria was positive health care system.[10] There are only a few studies comparing the efficiency of ADA and WHO criteria in diagnosing GDM.

Table 1: American Diabetes Association (ADA) and World Health Organisation (WHO) criteria for the diagnosis of Gestational Diabetes Mellitus (GDM)

	ADA	WHO
Fasting	≥ 5.1 mmol/L	≥ 7 mmol/L
1 hour	≥ 10.0 mmol/L	
2 hour	≥ 8.5 mmol/L	≥ 7.8 mmol/L

Hence this study was carried out to compare ADA criteria`s diagnostic accuracy and validity in diagnosing GDM and its complication considering WHO criteria as gold standard.

Materials and Methods

This study was conducted in Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India by department of Biochemistry. JIPMER is the tertiary care referral hospital located in the coastal region of Puducherry. JIPMER is providing service to people in Pondicherry, Karaikal and neighbouring districts of Tamilnadu. On an average 1, 10,000 outpatients and 20,000 in-patients are treated per year by the Department of Obstetrics & Gynaecology. Approximately 14,500 deliveries are conducted per year. This study was approved by Institute Research Council and Institute Ethics Committee. It was a combination of retrospective and a prospective study designs.

Study Design

The retrospective study consists of the analysis of the medical records pregnant women undergoing OGTT for 2 years (October 2013-14). In the prospective study design, universal screening of antenatal women who came to Obstetrics Outpatient Department around 24 weeks of gestation between October 2014 and October 2015 was done. Pre-gestational diabetic subjects were excluded.

The aim of the study was to compare ADA criteria's diagnostic accuracy and validity in detecting the prevalence and complication of GDM considering WHO criteria as gold standard. Informed written consent was obtained. Body Mass Index (BMI) was calculated using the formula (weight in kg) / (height in metre).[2] The fasting venous sample was collected. 75 gm of glucose was given orally following which 1 hour and 2-hour samples were collected. The serum glucose levels were analysed by glucose oxidation and peroxidation (GOD-POD) method by the autoanalyzer Olympus AU400.[11] The results were analysed using ADA guidelines in comparison with WHO (Table 1).

They were classified into 4 groups Normal glucose tolerance (NGT) by both criteria (Group I), GDM by ADA only (Group II), GDM by WHO only (Group III) and GDM by both criteria(Group IV). All GDM women regardless of the criteria followed were managed according to standard guidelines as per our institutional protocol.[8] They were followed up to delivery and mode of delivery (Vaginal vs. Instrumental vs. Lower segment caesarean section-LSCS) was noted. After delivery, the birth weight of the baby, Apgar score at 1 and 5 min were documented. Macrosomia was defined if the birth weight was > 3.5 kilograms.[12]

Statistical Analysis

The prevalence of GDM, the distribution of categorical data was expressed as frequencies and percentages. Continuous data was expressed as mean ± SD. Chi-square test / Fisher`s exact test was used to compare proportions and Independent t-test was used to compare mean of two groups. Sensitivity, specificity along with predictive values was calculated by considering WHO criteria as the gold standard for assessing the diagnostic power of ADA. Agreement between the criteria was assessed using kappa statistics. Data were analysed by International Business Machines Corporation Statistical Package for the Social Sciences (IBM-SPSS) Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp. All statistical analysis was carried out at 5% level of significance and p-value <0.05 was considered as significant.

Results

A total of 1189 cases were included in the study (563 in retrospective and 626 in prospective study). Ten patients (four in retrospective and six in prospective study) had pre-gestational diabetes and were excluded. Hence 1149 subjects (559 in retrospective and 620 in prospective study) data were collected. Mean fasting, one and two-hour glucose values of OGTT were 3.94 ± 0.61 mmol/L, 6.86 ± 1.60 mmol/L and 5.79 ± 1.45 mmol/L respectively. One hundred and six pregnant women (9.0%) were diagnosed to have GDM based on WHO criteria, whereas One hundred pregnant women (8.5%) were diagnosed by ADA criteria. Prevalence of GDM

Table 2: Classification of women by American Diabetes Association (ADA) and World Health Organisation (WHO) criteria

ADA		WHO criteria	
	GDM	NGT	Total
	N (%)	N (%)	N (%)
GDM	74(6.3)	26(2.2)	100(8.5)
NGT	32(2.7)	1047(88.8)	1079(91.5)
Total	106(9.0)	1073(91.0)	1179(100)

GDM: Gestational Diabetes Mellitus, NGT: Normal Glucose Tolerance

Table 3: Prevalence of Gestational Diabetes Mellitus by World Health Organisation (WHO) and American Diabetes Association (ADA) criteria

	GDM by WHO	GDM by ADA
Value	N(%)	N (%)
Fasting only	0 (0)	43 (3.7)
1 hour only	NA	34 (2.9)
2 hour only	99(8.4)	44 (3.7)
Fasting & 1	NA	21 (1.8)
Fasting & 2	7(0.6)	22 (1.9)
1 & 2	NA	32 (2.7)
All 3	NA	20 (1.7)
Total	106 (9)	100 (8.5)

Table 5: Comparison of study parameters between Gestational Diabetes Mellitus (GDM) and Normal Glucose Tolerance (NGT) group (Prospective study)

Parameters	GDM WHO (N=57)	GDM ADA (N=55)	NGT (N= 549)	p Value *(A vs. C)	p value *(B vs. C)
Age (years)	27.11 ± 4.7	27.4 ± 4.0	24.9 ± 4.0	0.0001#	0.0001#
Height(metre)	1.53 ± 0.06	1.54 ± 0.06	1.53 ± 0.06	0.407	0.59
Weight (kilogram)	65.6 ± 13.9	65.9 ± 14.4	58.90 ± 12.3	0.001#	0.001#
Body mass index (kg/m^2)	27.7 ± 5.5	27.9 ± 6.0	25.2 ± 5.3	0.001#	0.001#
Preeclampsia	4 (7.0%)	3 (5.5%)	6 (1.1%)	0.02#	0.08
Instrumental Delivery	3 (5.3%)	2 (3.6 %)	29 (5.3%)	0.646	0.8
Lower segment caesarian section	8 (14.0 %)	7 (12.7 %)	49 (8.9 %)	0.153	0.23
Birth weight (kg)	3.0 ±0 .5	2.9 ± 0.4	2.8 ± 0.3	0.003#	0.2
BW ≧3.5 kg	10(17.5%)	7 (12.7%)	25 (4.6%)	0.001#	0.086

BMI: Body mass index, LSCS: Lower segment caesarean section, BW: Birth Weight.
*A: GDM (WHO) group, B: GDM (ADA) group, C: Normal glucose tolerance (NGT) group.

in the study population positive by either one of the methods was 11.2% (132 women) and 88.8% (1073) had normal glucose tolerance by both the criteria (Table 2).

Agreement between ADA and WHO criteria was 0.69. Out of 106 women diagnosed by WHO, none of the cases were diagnosed by fasting value alone, whereas 2-hour criteria was met by all 106 subjects (Table 3). The GDM cases diagnosed by ADA values alone and in combination was represented in Table 3.

As all the cases were diagnosed by WHO second hour value, it was considered as gold standard and diagnostic accuracy of ADA criteria was compared against it (Table 4). Sensitivity and positive predictive value was less and specificity and negative predictive value of ADA was compared to WHO criteria.

GDM mothers by either criterion were significantly older and had increased weight and BMI when compared to NGT subjects. The majority of the study subjects had the vaginal delivery irrespective of their glycemic status. The difference in the prevalence of preeclampsia (p=0.02), macrosomia (p=0.001) and increased birth weight (p=0.003) were significant in GDM mothers diagnosed by WHO criteria alone when compared to subjects with normal glucose tolerance. But it was no significant by ADA criteria (Table 5). There was no difference in the Apgar score between the groups.

GDM mothers delivered babies with higher birth weight when compared to non-GDM mothers (Table 5). But WHO criteria identified more percentage of macrosomic babies when compared to ADA criteria (17.5% Vs 12.7%). Table 6 depicts the odds ratio of maternal and foetal outcomes between GDM and NGT group.

Table 6: Odds ratio of maternal and foetal outcomes between Gestational Diabetes Mellitus (GDM) diagnosed by World Health Organisation (WHO) and American Diabetes Association (ADA) criteria and Normal Glucose Tolerance (NGT) group (Prospective study)

Parameter	GDM WHO (N=57) NGT (N=549) Odds ratio with 95 % confident interval	GDM ADA (N=55) NGT (N=549) Odds ratio with 95 % confident interval
Preeclampsia	6.83 (1.9-24.9)	5.2 (1.3-21.9)
Instrumental Delivery	1 (0.3-3.4)	0.7 (0.2-2.9)
Lower segment caesarian section	1.7 (0.7-3.7)	1.5 (0.7-3.6)
BW ≥3.5 kg	4.5 (2.0-9.8)	3.1 (1.3-7.6)

Discussion

There is alteration in glucose homeostasis during pregnancy. About 3-8% of pregnancy was complicated by GDM which leads to maternal and foetal complications. Glucose intolerance may improve after delivery. But the risk of development of diabetes and metabolic syndrome after delivery increases, it is about 21.1% after ten years.[13,14] Hence this study was carried out to compare ADA criteria`s diagnostic accuracy and validity in diagnosing GDM and its complication considering WHO criteria as gold standard.

Prevalence of GDM in the study population positive by either one of the methods was nearly 11.2%. This is comparable to the previous study by Seshiah *et al*. in 2008.[15] Both the criteria have diagnosed GDM cases to a similar extent. Farrar et al. concluded in his study that both the criteria were comparable in identifying the GDM cases and predicting the risk of macrosomia, LSCS and instrumental delivery.[16] But a study done by Tran et al in Vietnam concluded

that WHO criteria diagnosed more GDM cases (24.3% vs. 20.4%) than ADA criteria[10] and a study by Dahanayaka NJ *et al*. from Srilanka reported that ADA criteria picked up more cases than WHO criteria.[17] This difference in prevalence is due to the difference in the ethnicity of the subjects, and whether universal or risk-based screening method was used in the study.

WHO 2-hour value identified all the cases of GDM, whereas fasting value alone didn't diagnose any case in both the study designs. Fasting ADA cut off picked up was 3.7%. This difference would be attributed to higher WHO fasting cut off value than ADA fasting cut off. Hence, the application of WHO 2-hour criteria is more than fasting criteria. Hence Diabetes In Pregnancy Study group India (DIPSI) recommends the usage of 2-hour value alone for GDM diagnosis.[18] But a study done by M. Santos-Ayarzagoitia et al. reports that the sensitivity and specificity of 100 gm ADA criteria were more when compared to WHO criteria.[19]

Seshiah *et al*. concluded that 2-hour glucose value of > 7.8 mmol/L following a glucose load of 75gm will serve as both as screening as well as diagnostic test.[20] Maria *et al*. reported that ADA criteria defined a more stringent condition for GDM diagnosis, and it identified more severe condition when compared to WHO criteria.[21] A prospective study done by Dahanayaka NJ *et al*. reported that 1 hour ADA criterion alone did not detect any cases and 2 hour value alone diagnosed 0.74% of cases,[17] whereas in this present study the pickup rate for 1 hour and 2 hour ADA criteria was 2.9% and 3.7% respectively.

GDM mothers were older, obese and had increased BMI than non-GDM mothers. These findings are similar to various studies that have shown that age and BMI were independent predictors of GDM.[22,23] Prevalence of preeclampsia in GDM mothers was high when compared to non- GDM mothers. This may be explained by the common risk factors like increased maternal age, obesity between GDM and preeclampsia.[24] Hence universal screening has been recommended instead of selective screening.[3]

In this study, WHO criteria were observed to predict both maternal and foetal complications of GDM at a higher rate significantly than ADA criteria which is in agreement with previous reports.[25,26] In a meta-analysis done by Poolsup et al. concluded that WHO criteria predicted GDM complications at a higher rate than ADA criteria and when these subjects were intervened at an early stage, they showed a significant reduction in complications like macrosomia and large for gestational age (LGA) birth, but there was no difference in caesarean rate when compared with controls.[27] The strength of this study was that it included all the patients who undertook glucose tolerance test were included. The shortcoming of the study was that maternal and fetal outcomes of the study subjects in the retrospective study would not be collected. The present study concludes that the prevalence rate of GDM by both the criteria were comparable. The complications of GDM were predicted at a higher rate by WHO than ADA criteria. Usage of WHO second-hour criterion alone is recommended as a one-step screening and diagnostic test to diagnose GDM. It will also help in reducing the cost of the health care delivery system as only one sample is required. Further studies are recommended to compare the effectiveness of WHO second-hour criterion alone as a one-step screening and diagnostic test to diagnose GDM and to compare the same with DIPSI criteria and other standardized criteria.

Acknowledgement: None

Conflict of interest: None

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How to cite this article: Arul Vijaya Vani .S, Suganya .S, Soundravally .R, Sagili .H, Niranjjan .R. Comparison of American Diabetes Association (ADA) and World Health Organization (WHO) criteria in the screening and diagnosis of gestational diabetes mellitus in South Indian population. *Int J Clin Biochem Res* 2019;6(2):234-8.