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Original Research

Gestational Diabetes Mellitus and Feto-Maternal Outcomes in Federal Medical Centre, Yenagoa, Bayelsa State-A Comparative Study of Two Diagnostic Criteria

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Abstract

Background: The prevalence of gestational diabetes mellitus (GDM) is dependent on the diagnostic criteria used and there is no consensus on screening methods and diagnostic criteria. The International Association for Diabetes in Pregnancy Study Group (IADPSG) recently put forward new diagnostic criteria and encourages its adoption worldwide. The aim of this study was to determine the incidence of GDM and to compare the foeto-maternal outcomes of women diagnosed with GDM in the Federal Medical Centre, Yenagoa using the WHO 1999 and IADPSG criteria.

Methodology: This was a cohort study of 340 women who were booked for antenatal care at the Federal Medical Centre, Yenagoa. Women who gave consent to participate in this study took part in a 75-gram, 2-hour oral glucose tolerance test (OGTT). The diagnosis of GDM was sought in each participant using both the WHO 1999 and the IADPSG criteria. The incidence and the foeto-maternal outcomes in women diagnosed with GDM using different criteria were compared.

Results: The incidence of GDM was 5.3% in the IADPSG (case) group and 3.8% in the WHO (control) group. This difference was not statistically significant ($p = 0.18$). There was no significant difference between the groups for foetal and maternal outcomes that were assessed. Maternal outcomes were pre-eclampsia ($p = 0.48$), polyhydramnios ($p = 0.31$), insulin therapy ($p = 0.35$), caesarean section ($p = 0.28$), genital tract laceration ($p = 0.18$) and instrumental vaginal delivery ($p = 0.34$). Foetal outcomes were birth weight ≥ 4kg ($p = 0.07$), neonatal jaundice ($p = 0.38$), hypoglycaemia ($p = 0.46$), birth injuries ($p = 0.42$) and shoulder dystocia ($p = 0.23$).

Conclusion: The application of the IADPSG criteria in our environment may lead to an increase in the number of women being managed for GDM without any appreciable improvement in foetal and maternal outcomes.

Keywords: *Gestational Diabetes Mellitus; Foeto-Maternal Outcomes; IADPSG Criteria; WHO 1999 Criteria.*

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Introduction:

Gestational diabetes mellitus (GDM) is glucose intolerance of varying severity with onset or first recognition in the index pregnancy[1,2]. It is associated with poor perinatal outcomes, increased maternal morbidity, an increased need for maternal hospitalization and occasionally, maternal mortality. Gestational diabetes mellitus has been shown to have lifelong effects for both the mother and her offspring and the condition has been shown to put a considerable burden on available health care resources[3]. Making a diagnosis of GDM in pregnancy and employing appropriate management options has the ability to reduce the occurrence of adverse neonatal and maternal outcomes[4–6].

Globally, about 1-14% of pregnancies are complicated by gestational diabetes mellitus[7,8]. The prevalence in Africa has been described to range between 10% and 13.9% and in Nigeria, it ranges between 1.5% and 13.9%[2,7,9]. The reported prevalence depends on the screening method used and the diagnostic criteria applied[8]. Strategies for the screening of GDM could either be universal or selective[2-7].

The first criteria for the diagnosis of GDM were first published by O'Sullivan and Mahan in 1964[10]. Since then, there have been various criteria for the diagnosis of GDM. While the O'Sullivan criteria were based on the risk of a woman developing type 2 Diabetes Mellitus after pregnancy, some of the other criteria were made based on glucose levels considered to be diabetic in non-pregnant individuals[10,11]. The latest criteria for the diagnosis of GDM as proposed by the International Association of Diabetes and Pregnancy Study Group (IADPSG) in 2010 and the World Health Organisation (WHO) in 2013 are based on the results of the Hyperglycaemia and Adverse Pregnancy Outcomes (HAPO) study which was concluded in 2008.

The HAPO study correlated adverse pregnancy outcomes to levels of hyperglycaemia noted during the course of pregnancy[4,11,12] and was able to prove that adverse maternal and perinatal outcomes could occur at levels of hyperglycaemia that were thought not to be sufficiently high enough to merit a diagnosis of GDM. The results of the study showed that for every increase in glucose level, there was a corresponding increase in the risk of an adverse foetal or maternal outcome.

Based on the HAPO study, the IADPSG recommended that universal screening for GDM be performed and that a 75-gram, 2-hour oral glucose tolerance test (OGTT) be used for the screening procedure and a single abnormal glucose value was sufficient to make a diagnosis of GDM. Plasma glucose values for the diagnosis of GDM as recommended by the IADSPSG are a fasting level of ≥5.1mmol/L, 1-hour post-OGTT level of ≥10.0mmol/L and a 2-hour post-OGTT value of ≥8.5mmol/L.

There have been a myriad of responses following the recommendations of the WHO and the IADPSG regarding the diagnosis of GDM. Several studies have shown that the new recommendations lead to an increase in the prevalence of GDM[5,13–15]. This has led to concerns of increased cost of care, increased workload for health care staff and acceptability of the practice of universal screening by pregnant women[4,11,15,16].

The criteria used in making a diagnosis of GDM in Nigeria, like in many other parts of the world, do not appear to be uniform. The Diabetes Association of Nigeria (DAN) has recommended that selective screening be performed for pregnant women based on known risk factors for GDM and women identified to have risk factors undergo an OGTT for diagnosis[17]. The criteria put forward by the WHO in 1999 following a 75-gram, 2-hour OGTT, plasma fasting glucose ≥7.0 mmol/L and/ or 2 hours postprandial glucose ≥ 7.8 mmol/L, is currently being used for the diagnosis of GDM in the FMC Yenagoa and appears to be commonly used in Nigeria[2,3,9].

Failure to diagnose a patient with GDM amounts to a double tragedy since the risks to both mother and foetus are unmitigated and the neonate born has long-term risks that were created by the hyperglycaemic environment it was exposed to in-utero[1,11,18].

It is the aim of this study therefore to determine the prevalence and foeto-maternal outcomes of women diagnosed with GDM using the WHO 1999 criteria compared to the prevalence and foeto-maternal outcomes of women diagnosed with GDM using the IADPSG criteria. This study will provide evidence to determine if there should be a paradigm shift to universal screening of pregnant women and if the IADPSG criteria should be adopted.

Methodology

This was a cohort study conducted between January and June 2019 involving340 pregnant women booked for antenatal care in the Federal Medical Centre, Yenagoa, Bayelsa State whose pregnancies were between 24- and 34-weeks gestational age. Patients who met the inclusion criteria and gave their consent were selected to participate in the study by simple random sampling. All women with pre-gestational diabetes mellitus or other endocrine disorders e.g. hyperthyroidism, Cushing's syndrome or Conn's syndrome were excluded from the study. Also excluded were women on Highly active antiretroviral therapy or steroid therapy.

A proforma designed for this study was used to collect information on the history and examination findings of each participant. Participants were asked to maintain their normal diet for at least three days prior to the study and then maintain an 8-hour overnight fast prior to the study. On the day of the study, a 75-gram, 2-hour OGTT was administered. Samples were analysed using an ACCU-CHECK® glucometer (Model GU, serial number GU05694841, Roche™). To check the validity of the results obtained from the glucometer, 2mls of venous blood were randomly collected from 10 different participants on each day the study was conducted and placed in a fluoride oxalate bottle and a portion of these samples were assayed using the glucometer the other portion was sent to the laboratory for assay using a spectrophotometer. The results were compared and found to be similar.

The results obtained were interpreted using both the IADPSG criteria and then the WHO 1999 criteria. Women who were diagnosed with GDM using either criterion were treated according to the departmental protocol and were followed up till delivery where foetal and maternal outcomes were documented. The foetal and maternal outcomes of those diagnosed with GDM using either criterion was compared. Results that were classified as GDM using the WHO 1999 criteria were taken as the control group and those that were classified using the IADPSG criteria were taken as the cases.

Maternal outcomes associated with GDM that were assessed for in both arms of the study included the need for insulin in glucose control, pre-eclampsia, abdominal delivery, genital tract laceration and instrumental vaginal delivery were noted during the antepartum and intrapartum periods. Foetal outcomes that were recorded for both arms of the study were birth weight ≥4kg, sudden intrauterine foetal death, shoulder dystocia, birth injuries, neonatal hypoglycaemia (random blood sugar of ≤2.6 mmol/L using a capillary blood sample obtained by a heel prick between 5-10 minutes of delivery of the baby and analysed using the glucometer described earlier), neonatal jaundice (laboratory identification with unconjugated bilirubin of ≥ 204 mmol/L/kg) and early neonatal death (neonatal demise within 7 days of delivery).

Data analysis was done using the Statistical Package for Social Science (SPSS) version 20. Descriptive data were presented in tables and figures. Means and standard deviations were calculated for continuous variables. The association between variables was tested using Chi-square test or Fisher's exact test for categorical data and the student's t-test for continuous data. Logistic regression was used to assess the contribution of each risk factor to the foetal and maternal outcomes assessed. The level of significancewas set at $p < 0.05$. Approval for this study was given by the Ethical Review Committee of the Federal Medical Centre, Yenagoa.

Results

A total of three hundred and fifty-one women were recruited for this study. Eleven women did not complete the OGTT as four complained of nausea after taking the glucose drink and chose to opt out of the study, two women vomited shortly after taking the glucose drink and were excluded from the study. These six women were referred for appropriate care. The other five women complained about their inability to tolerate the hunger pangs they were experiencing prior to the completion of the study and chose to opt out so they could eat. Thus, only three hundred and forty women completed the OGTT and obtained their results. Women diagnosed with GDM by either criterion were followed up to delivery and then the outcomes of the study were recorded.

Table 1 shows the sociodemographic characteristics of the participants. The mean age of the women who participated in the study was 30.9 ± 4.3 years and ranged between 17 and 43 years. There were more married women 321 (94.4%) than single women 19 (5.6%). Women with primary education were 15 (4.4%), secondary education 145 (42.6%) and 180 (53%) with tertiary level of education. One hundred and eleven (32.7%) women were nulliparous, 95 (27.9%) were primiparas, 109 (32.1%) were multiparas and 25 (7.4%) were grandmultiparas. The mean gestational age of participants was 30.0 ± 2.6 weeks and ranged between 24 and 34 weeks.

Using the WHO 1999 criteria, 13 (3.8%) women were found to have GDM while with the criteria put forward by the IADPSG, 18 (5.3%) women were found to have GDM. There was no statistical difference in the occurrence of GDM using either the IADPSG criteria (cases) or the WHO 1999 criteria (controls) $p = 0.23$, OR 1.41 (0.68-2.91) (see table2).

Amongst women with risk factors, 16/131 (12.2%) among the cases were diagnosed as having GDM while 12/131 (9.2%) were diagnosed with GDM in the control group. This difference was not statistically significant $p = 0.27$, OR 1.38 (0.63-3.04) (table 2).

The frequency of GDM women without risk factors was 2/209 (0.95%) in the case group and 1/209 (0.47%) in the control group. This was also not a statistically significant difference $p = 0.50$, OR 2.01, (0.18-22.34) (see table 5.2).

The odds of a woman without risk factors for GDM becoming a case (IADPSG criteria) were calculated it was noted that in the absence of risk factors for GDM, it was unlikely that a woman would be identified as a case $p = 0.02$, OR 0.06 (0.02-0.31). However, it was more likely for a woman with risk factors for GDM to be identified as a case $p = 0.00$ OR 14.33 (3.25-63.43) (table 2).

Maternal and foetal outcomes in those diagnosed with GDM are displayed in Table 3. Maternal outcomes that were assessed for were pre-eclampsia, polyhydramnios, use of insulin for control of blood sugar, caesarean delivery, genital tract laceration and instrumental vaginal delivery. In the case group, 4 (22.22%) women were found to have pre-eclampsia. In the control group, the frequency of pre-eclampsia was 3 (23.07%). This difference was not statistically significant $p = 0.64$ OR 0.95 (0.17 – 5.22).

In the case group, 4 (22.22%) of women had polyhydramnios as against 4 (30.77%) of women in the control group. This difference was not statistically significant p = 0.45, OR 0.64 (0.13-3.25).

Seven women (38.89%) (46.15%) required insulin therapy for the control of blood sugar in the IADPSG (case) group compared to six women (46.15%) diagnosed using the WHO 1999 (control) criteria. This difference was not statistically significant p = 0.48, OR 0.74 (0.17-3.14).

Regarding the route of delivery, 9 (50%) in the IADPSG (case) group had an abdominal delivery as against 8 (61.54%) women in the WHO 1999 (control) group. This difference was not statistically significant p = 0.56, OR 0.86 (0.21 – 3.58).

Four (22.22%) in the IADPSG (case) group had a genital tract laceration during delivery as compared to one (7.69%) woman in the WHO 1999 (control) group. This difference was not statistically significant p = 0.28, OR 3.42 (0.33-34.99).

Three (16.67%) in the IADPSG (case) group and three women (23.07%) women in the WHO 1999 (control) group had instrumental vaginal deliveries. This difference was not statistically significant p = 0.60 OR 0.84 (0.14-5.07).

Foetal outcomes assessed in the study were macrosomia, neonatal jaundice, hypoglycaemia, birth injuries, shoulder dystocia and perinatal death. There was no case of perinatal mortality amongst the women diagnosed as having GDM in this study.

Six (33.3%) macrosomic babies were born to women diagnosed as having GDM using the IADPSG (case) criteria as compared to eight (61.54%) macrosomic babies were born to women diagnosed as having GDM using the WHO 1999 (control) criteria. The risk for having a macrosomic baby was not statistically different using either criteria p = 0.11, OR 0.31(0.07-1.38).

Ten (55.55%) babies born to women in the IADPSG criteria (case group) had neonatal jaundice as compared to eight (61.54%) babies born with neonatal jaundice born to women diagnosed using the WHO 1999 (control) criteria. The risk of neonatal jaundice was not significantly different when GDM was diagnosed with either criteria p = 0.51, OR 0.78 (0.18-3.34).

Hypoglycaemia occurred in 8 (44.40%) of babies born to women in the IADPSG criteria (case) group while it occurred in 6 (46.15%) of those born to women in the WHO 1999 criteria (control) group. This difference was not statistically significant p = 0.61, OR 0.93 (0.22-3.91).

Birth injury occurred in one (5.55%) baby born to a woman in the IADPSG criteria (case) group and in one (7.69%) baby born to a woman in the WHO 1999 criteria (control) group. The odds of a birth injury were not significantly different with either criteria p = 0.67, OR 0.71(0.04-12.43).

There was the occurrence of shoulder dystocia in 2 (11.11%) of babies born to women in the IADPSG criteria (case) group. Two (15.38%) cases of shoulder dystocia also occurred in the WHO 1990 criteria (control) group. This difference was not statistically significant p = 0.59, OR 0.73 (0.09-6.04)

Table 1: Sociodemographic Characteristics of Participants

Variable	**Number (%)**
Age	Mean Age 30.9 ± 4.8
17 – 24	32 (9.4)
25 – 34	237 (69.7)
35 – 45	71 (20.9)
Marital Status	
Single	19 (5.6)
Married	321(94.4)
Educational Status	
Primary	15 (4.4)
Secondary	145 (42.6)
Tertiary	180 (53)
Parity	
Nullipara	111 (32.7)
Primipara	95 (27.9)
Multipara	109 (32.1)
Grand multipara	25(7.4)
Risk Factors	
Present	131 (38.5%)
Absent	209 (61.5%)
Mean Gestational Age	30.0 ± 2.6

Table 2: Showing diagnosis of GDM among study participants

Variable	**WHO 1999**	**IADPSG**	
	Number (%)	Number (%)	P value OR (95% CI)
Prevalence of GDM	13/340 (3.8)	18/340 (5.3)	p = 0.23 1.41 (0.68-2.91)
Prevalence of GDM in women with risk factors	12/131 (9.2)	16/131 (12.2)	p = 0.27 1.38 (0.63-3.04)
Prevalence of GDM in women without risk factors	1/209 (0.47)	2/209 (0.95)	p = 0.50 2.01(0.18 – 22.34)
Likelihood of GDM among cases (IADPSG) with risk factors	NA*	16/131	P< 0.01 OR 14.33 (3.23-63.43)
*NA – Not Applicable			

Table3: Showing association of GDM and Feto-Maternal Outcomes

Variable	WHO 1999 Number (x/13) (PERCENTAGE)	IADPSG Number (x/18) (PERCENTAGE)	P= x OR (95% CI)
Maternal Outcomes			
Pre-eclampsia	3 (23.07)	4 (22.22)	P = 0.64 0.95 (0.17-5.22)
Polyhydramnios	4 (30.77)	4 (22.22)	p = 0.45 0.64 (0.13-3.25)
Insulin therapy	6 (46.15)	7 (38.89)	p = 0.48 0.74 (0.17-3.14)
Caesarean section	7 (61.54)	9 (50)	p = 0.56 0.86 (0.21-3.58)
Genital tract laceration	1 (7.69)	4 (22.22)	p =0.28 3.42 (0.33-34.99)
Instrumental vaginal delivery	3 (23.07)	3 (16.67)	p = 0.60 0.84 (0.14-5.07)
Neonatal Outcomes			
Birth weight ≥ 4kg	8 (61.54)	6 (33.33)	p = 0.11 0.31 (0.07 -1.38)
Neonatal Jaundice	8 (61.54)	10 (55.55)	p = 0.51 0.78(0.18 – 3.34)
Hypoglycaemia	6 (46.15)	8 (44.44)	p = 0.61 0.93 (0.22 – 3.91)
Birth injuries	1 (7.69)	1 (5.55)	p = 0.67 0.71 (0.04 – 12.43)
Shoulder dystocia	2 (15.38)	2 (11.11)	p = 0.59 0.73 (0.09- 6.04)

Discussion

The results from this study show a higher occurrence of gestational diabetes mellitus in the case group (5.3%) than in the control group (3.8%). Statistical analysis showed that this difference was not significant [p = 0.23, OR 1.41 (0.68-2.91)]. Comparing the frequency of GDM diagnosed using different criteria, Olagbuji et al in their cross-sectional study[5] showed that the incidence of GDM more than doubled (2.2) with the IADPSG criteria as compared to the WHO 1999 criteria. A test of significance was not carried out on the results obtained by Olagbuji et al[5]. Similarly when OGTT results were retrospectively reviewed by Benhalima et al[13] and Meek et al[19], they found an increase in the incidence of GDM. The increases found were mainly a result of the reduced fasting blood glucose level of 5.1 mmol/L used in the IADPSG criteria as against the 5.3 mmol/L set by the Carpenter and Coustan criteria which was the benchmark in the retrospective analysis by Benhalima et al[13] and the 5.6mmol/L which was set by NICE which was the benchmark in the study by Meek et al[19]. In the studies by Benhalima et al[13] and Meek et al[19], no statistical tests were performed to determine if there was any difference in the results obtained.

In this study, the diagnosis of GDM was made exclusively using the fasting blood glucose levels in 33% of the cases (IADPSG criteria) and in none of the controls. The incidence of GDM in this study using the IADPSG criteria was 1.3 times higher than the incidence with the WHO criteria. This increase is modest compared to the difference in the study by Olagbuji et al[5] but the same as the difference of 1.3 found when Imoh et al[20] compared the difference in the incidence of GDM using the IADPSG criteria and the WHO criteria. This difference demonstrates the impact of the reduced fasting blood glucose levels used by the IADPSG criteria.

Regarding the issue of universal screening which is recommended by the IADPSG[12] as against selective screening which is widely practised in Nigeria[2] and recommended by DAN[17]. Amongst women identified as cases (IADPSG criteria) in this study, most had risk factors for GDM and there was a significant association between the presence of risk factors and a diagnosis of GDM. The chances of being identified as a case (IADPSG criteria) was 14 times more likely (OR-14.33 [95% CI (3.23 – 63.43)] p = 0.00) when a woman had risk factors for GDM. There was no statistically significant difference in the occurrence of GDM in the presence of risk factors when the groups were compared (OR- 1.38 [95% CI (0.63 – 3.04)] p = 0.27).

Olagbuji et al[5] showed that up to 20% of women who did not have a risk for GDM could end up with GDM but in this study, less than 1% of women in either group had GDM, and this difference was not statistically significant [p = 0.5, OR 2.01 (0.18-22.34). Colagiuri et al[4] suggested that each facility determine what works best for it after taking into consideration, the resources available to it.

The difference in the occurrence of foeto-maternal outcomes between the groups in this study was not statistically significant. The HAPO study[12] was designed to identify, with a view to mitigate poor foetal and maternal outcomes that occurred at lower levels of hyperglycaemia that would not have been considered as GDM using older criteria. However, in this study which used the WHO 1999 criteria as a control, we found no statistically significant difference in the foeto-maternal outcomes.

Findings from this study showed a higher incidence of GDM in the case group than in the control group and this is in keeping with the consensus that the frequency of GDM is higher with the IADPSG criteria than with the WHO 1999 criteria[5, 13]. The difference in the prevalence obtained from the groups was not statistically significant.

Although GDM occurred in women with no risk factors, there was a statistically significant association between the diagnosis of GDM in the case group and the presence of risk factors for GDM. This is

important because universal screening is advocated for when the IADPSG criteria are used[21] and carrying out universal screening may introduce logistical challenges in a resource-constrained setting.

The use of a glucometer rather than a spectrophotometer was a consequence of the high cost of conducting the study and is a limitation of the study. The veracity of the results obtained was assured by the constant cross-checking of results obtained with the glucometer with results obtained using a spectrophotometer.

Conclusion:

The application of the IADPSG criteria in our environment may lead to an increase in the number of women being managed for GDM without any appreciable improvement in foetal and maternal outcomes. Therefore, centres in resource-challenged settings should maintain the use of the WHO 1999 criteriain the diagnosis and management of GDM. There is a need to continue collecting data on outcomes of pregnancies in which GDM is diagnosed using the IADPSG criteria as this may lead to a change in policy in the future.

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