

## Original Article

# Diagnostic Accuracy of Random Plasma Glucose and Random Blood Capillary Glucose in Detecting International Association of Diabetes and Pregnancy Study Groups- Defined Hyperglycemia in Early Pregnancy

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### ABSTRACT

**Background:** Maternal hyperglycemia first diagnosed in pregnancy, previously referred to as gestational diabetes mellitus is associated with health consequences for both the mother and her fetus/baby, not only in the short term but also in the long term. Early screening helps to identify women with overt diabetes or those with early onset GDM. **Aims:** The aim of this study was to determine the diagnostic performance of two screening tests (Random plasma glucose, Random capillary glucose) in relation to 75g Oral glucose tolerance test (OGTT) done before 24 weeks gestation. **Methods:** This prospective longitudinal cohort study was carried out between 1<sup>st</sup> February, 2017 and 31<sup>st</sup> July, 2017, at two teaching hospitals in Nigeria. Two hundred and eighty one (281) pregnant women who met the inclusion criteria were selected and screened with both random plasma glucose (RPG) and random capillary glucose (RCG) before 24 weeks of pregnancy. They were then made to undergo 75g OGTT a week later. The diagnostic performance of the screening tests were determined. **Results:** A total of 270 women had 75g OG. **Conclusion:** Random plasma glucose and Random capillary glucose performed poorly compared to 75g-OGTT in detecting hyperglycemia in early pregnancy.

**KEYWORDS:** Hyperglycemia, pregnancy, random capillary glucose, random plasma glucose

## INTRODUCTION

Insulin resistance and hyperinsulinemia associated with pregnancy may predispose some women to gestational diabetes.<sup>[1]</sup> Until recently, maternal hyperglycemia first diagnosed in pregnancy was referred to as Gestational Diabetes Mellitus (GDM)<sup>[1]</sup> which was then defined as any degree of glucose intolerance with onset or first recognition during pregnancy.<sup>[1]</sup> Hyperglycemia in pregnancy emerged to be more appropriate as suggested by Endocrine society as this definition of GDM does not exclude the possibility of unrecognized glucose intolerance that predates the pregnancy.<sup>[2]</sup> The International Association of Diabetes and Pregnancy Study Groups (IADPSG) classifies hyperglycemia first detected during pregnancy (HFDP) as either ‘overt diabetes’ or Gestational Diabetes Mellitus (GDM)<sup>[3]</sup> while The World Health Organization (WHO) in 2013

recommended that hyperglycemia first detected during pregnancy be classified as either ‘Diabetes Mellitus in Pregnancy (DIP)’ or GDM.<sup>[4]</sup>

Hyperglycemia first detected in pregnancy is associated with increased maternal and perinatal morbidity and mortality. It is one of the commonest endocrine disorders of pregnancy.<sup>[5]</sup> The prevalence of Hyperglycemia First Diagnosed in Pregnancy (HFDP) varies from 1-20% and is rising worldwide due to increased prevalence of obesity and Type 2 Diabetes Mellitus (T2DM).<sup>[5]</sup> Women

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of African, Hispanic, Indian and Asian origins have elevated risk than Caucasian women.<sup>[5]</sup> Recently, the prevalence of HFDP has increased by 2-3 folds ranging from 8.9-53.4%<sup>[6]</sup> due mainly to adoption of the newly proposed IADPSG criteria on screening and diagnosis of GDM.<sup>[3]</sup>

Hyperglycemia has health consequences for both the mother and her offspring not only in short term, but also in the long term.<sup>[7]</sup> Untreated hyperglycemia results in poor maternal and fetal outcomes. Pregnant women are more prone to preeclampsia, operative delivery and stillbirth<sup>[7]</sup> and infants are at higher risk of preterm delivery and macrosomia or large for gestational age which is associated with birth injury, respiratory distress and neonatal hypoglycemia.<sup>[7]</sup> Evidence showed that overt diabetes in pregnancy was associated with a twofold risk of congenital anomalies, preeclampsia and shoulder dystocia and a threefold risk of perinatal deaths. In the long term, children born to mothers with HFDP are at greater risk of obesity and type 2 DM in later life, a phenomenon traceable to the effects of intrauterine exposure to hyperglycemia.<sup>[7]</sup>

Fortunately, many of these risks associated with HFDP can be reduced by prompt identification to reduce maternal antenatal hyperglycemia.<sup>[7,8]</sup> There are multiple dimensions to the diagnosis of HFDP. Screening for hidden hyperglycemic tendency is initially done through simple biochemical method, while later confirmation of the presumptive diagnosis is done through some definitive tests.<sup>[8]</sup> Presently, there is marked degree of heterogeneity related to the diagnostic criteria of pregnancy hyperglycemia.<sup>[8]</sup> Unfortunately, there is no international consensus on the screening and diagnostic criteria for HFDP.<sup>[9]</sup> The controversies about the need to screen for hyperglycemia was finally put to rest following the result of the HAPO study which showed a continuum of risk between maternal glucose levels and adverse pregnancy outcome. The HAPO study also used a 2-hour glucose test as a single screening and diagnostic test and based on this study the International Association of Diabetes in Pregnancy Study Group (IADPSG) criteria were developed.<sup>[3,10]</sup> The IADPSG criteria was endorsed by many professional bodies and in 2013 the WHO also endorsed the IADPSG criteria as against the earlier 1999 WHO criteria.<sup>[3,4]</sup>

Current evidence suggests that early detection and management of hyperglycemia improves outcome for both mother and newborn.<sup>[6]</sup> Screening before 24<sup>th</sup> week of pregnancy helps to identify women with overt diabetes in pregnancy or those with GDM early in pregnancy.

Early diagnosis affords opportunity to prevent these complications. However, WHO's conclusion is that it is not certain if diagnosing and treating hyperglycemia before the usual window of 24-28 weeks gestation offers any benefit.<sup>[4]</sup>

The commonly used 50-g glucose challenge test (GCT) has several limitations; it is relatively expensive and considered unpleasant by many women.<sup>[11]</sup> It is also affected by the time of last meal<sup>[12]</sup> and has a poor reproducibility,<sup>[12]</sup> and the same criticism applies to the one step OGTT.<sup>[11]</sup> Therefore more reliable, easy to perform and cheap screening tests are needed especially in resource limited countries.<sup>[11]</sup> It is likely that Random plasma glucose and Random capillary glucose would be associated with higher screening uptake because of their feasibility at prenatal clinics. Random plasma glucose and random capillary glucose are both forms of random blood glucose. OGTT is indicated when random blood glucose is 5.5-11 mmol/L.<sup>[13]</sup>

This study was designed to determine the sensitivity, specificity and predictive values of random plasma glucose (RPG) and random capillary glucose (RCG) in detection of maternal hyperglycemia of early pregnancy using the 2010 IADPSG cutoffs for 75G OGTT. The appropriate diagnostic thresholds for our obstetric population was also determined using the receiver operating characteristics (ROC) analysis.

## METHODS

### Study area

This study was carried out among antenatal patients with gestational age less than 24 weeks at Federal Teaching Hospital, Ido Ekiti and Ekiti state university teaching hospital, Ado Ekiti. Approvals were obtained from ethics committees of the two teaching hospitals dated 18<sup>th</sup> July, 2016 and 19<sup>th</sup> August 2016.

### Study design

This was a prospective longitudinal cohort study carried out between 1<sup>st</sup> February 2017 and 31<sup>st</sup> July 2017.

### Sample size

The sample size was calculated with the formula  $N = Z^2pq/d^2$ <sup>[14,15]</sup> using 8.6% prevalence of hyperglycemia,<sup>[14]</sup> giving 120.78 participants. Since about 10 participants may be positive for HFDP out of the 120 using the above prevalence, the calculated sample size was adjusted (in order to obtain the same precision) by multiplying by 2 (the design effect factor) to get  $N = 240$  plus 10% attrition rate resulting in total sample size of 264. Therefore, a total sample size of 270 subjects who met the inclusion criteria were recruited within the 6 month duration of the study.

### Sampling technique and data collection

Convenience sampling technique was used where consecutive consenting pregnant women who met the inclusion criteria were recruited. The inclusion criteria were women with singleton viable gestation less than 24 weeks who presented for antenatal care while the exclusion criteria included pregnant women with known history of diabetes mellitus, those who were unsure of their LMP and had no early ultrasound report or women who declined consent for the study. Other exclusion criteria were women with multiple gestation or with chronic medical conditions like chronic hypertension, sickle cell disease, thyroid, liver and renal diseases, likewise those on drugs that can affect glucose tolerance such as steroids and salbutamol. The data were collected using structured questionnaires. Participants were educated about the study and their consent taken. The procedures followed were in accordance with the ethical standards of the two teaching hospitals and with the Helsinki Declaration of 1975, as revised in 2000. Research and laboratory assistants were then trained on how to administer the questionnaires and take blood samples. At the points of recruitment for the study, the participants were interviewed with a pretested proforma and the following information was recorded: age, parity, gestational age, ethnic group, religion, level of education, marital status, coexisting medical conditions and presence of risk factors for GDM (first degree relatives with DM, previous recurrent spontaneous miscarriage, previous delivery of baby with congenital malformations, or that weighed more than 4 kg). Gestational age was calculated from last menstrual period where it was known or with an early ultrasound scanning report if LMP was not known. The height and weight of participants were then recorded and their BMI calculated to assess for obesity.

The socioeconomic status of the participants was determined using Olusanya's<sup>[16]</sup> model that adopted respondent's educational status and husband's occupation. Scores of 1 and 2 were classified as upper socioeconomic class, a score of 3 as middle class, while scores of 4 and 5 were classified as lower class.

The subjects were then educated regarding the procedure for the screening. Venous blood was drawn (3 ml) into fluoride oxalate specimen bottles to prevent glycolysis and also a finger prick test was performed to obtain a drop of capillary blood for random capillary blood sugar. The finger prick pen was used each time with a new disposable lancet for all subjects. Samples taken in specimen bottles were then transported to the hospital central laboratory within 1 hour for analysis, while capillary blood sample were analyzed by photometric

detection in 25 seconds by Accu-check Active (Rosche Diagnostics) glucometer.

The subjects were then educated regarding the procedure for 75g OGTT and given appointments to be seen a week later. They were required to have fasted overnight for 8-12 hours before the test and to come to the clinic before 8.00 am on the morning of the test. All the participants remained in the clinic for the minimum of 3 hours without eating, drinking, smoking or sleeping while the test was being conducted. All medications likely to affect the test would have been discontinued a day before.

They were made to rest for a minimum of 15 minutes, then 3 ml of fasting venous blood sample was collected into fluoride oxalate specimen bottles and labelled appropriately before being given the 75g anhydrous glucose in 200-250 ml of water to drink within 5 minutes, then 3 ml of venous blood samples were taken into fluoride oxalate bottles at 1 hour and 2 hours after from time zero. The collected blood samples in fluoride oxalate bottles were allowed to stand for 15 minutes in the chemical pathology laboratory and the supernatant plasma separated and refrigerated at 2-8°C until analysis within 24 hours. The glucose loads were weighed using the triple beam balance (Ohaus<sup>R</sup>) and the plasma glucose analysis was done under the supervision of an experienced chemical pathologist in the hospital's chemical pathology laboratory.

Diagnosis of hyperglycemia in pregnancy was based on the IADPSG<sup>[3]</sup> criteria requiring at least one plasma glucose values to meet or exceed the following: 92 mg/dl (5.1 mmol/L) fasting, 180 mg/dl (10 mmol/L) one hour and 153 mg/dl (8.5 mmol/L) 2 hours, respectively.

### Statistical analysis

All data was entered in SPSS version - 20. Descriptive statistics was used for demographic and baseline data and summarized as mean, standard deviation and percentages as appropriate. Comparison between categorical variables was evaluated using the Chi-square test with Yate's correction or the Fisher's test as appropriate and continuous variables using the Student *t*-test. A *P* value of < 0.05 was considered statistically significant (Confidence level = 95%).

Area under the curve (AUC) was calculated through Receiver operating characteristic (ROC) analysis for different cut off of RPG and RCG against the 75g OGTT standard. Diagnostic performance parameters of RPG and RCG were then calculated including sensitivity, specificity, predictive values and overall efficiency against 75g OGTT done before 24 weeks as reference standard.

## RESULTS

A total of 281 women who fulfilled the inclusion criteria were involved in the study. Eleven women did not present for the OGTT and were lost to follow up, therefore results from a total number of 270 women were included in the final analysis. A total of 20 participants were diagnosed with hyperglycemia before 24 weeks using 75g OGTT giving a prevalence rate of 7.4%.

Table 1 shows the socio-demographic variables of the study participants. All the subjects were within the reproductive age group of 18-43 years with more than 80% being above 26 years. The mean (SD) age of the participants was 30.41 (4.69) years. More

than 90% of the respondents were married with only 5.9% being single. The participants were mostly Christians (94.4%) and of Yoruba ethnicity (87.8%) having tertiary level of education (75.2%). Majority were also professional (43.3%) belonging to the middle socio-economical class (43.7%).

The mean (SD) gestational age at recruitment was 19.00 (3.39) weeks and ranged from 8-23 weeks. Most respondents were multigravidas (67.4%). Table 1 also shows that majority of women with hyperglycemia belonged to 31-35 year age group (10.9%) while none was above 40 years. All of them were married and predominantly Christian (7.5%) with equal distribution between lower and middle socio-economic class.

**Table 1: Demographic characteristics of women with hyperglycemia detected before 24 weeks**

Variable	Hyperglycemia		Total n (%)	$\chi^2$	P
	Present n (%)	Absent n (%)			
Age group (years)					
≤ 25	2 (6.3)	30 (93.8)	32 (11.9)	5.552 <sup>Y</sup>	0.235
26-30	3 (2.8)	104 (97.2)	107 (39.6)		
31-35	10 (10.9)	82 (89.1)	92 (34.1)		
36-40	5 (14.7)	29 (85.3)	34 (12.6)		
41-45	0 (0.0)	5 (100.0)	5 (1.9)		
Marital status					
Single	0 (0.0)	16 (100.0)	16 (5.9)	0.455 <sup>Y</sup>	0.500
Married	20 (7.9)	234 (92.1)	254 (94.1)		
Ethnic group					
Hausa	0 (0.0)	2 (100.0)	2 (0.7)	1.189 <sup>Y</sup>	0.756
Igbo	2 (7.4)	25 (92.6)	27 (10.0)		
Yoruba	17 (7.2)	220 (92.8)	237 (87.8)		
Others	1 (25.0)	3 (75.0)	4 (1.5)		
Religion					
Islam	1 (7.7)	12 (92.3)	13 (4.8)	1.152 <sup>Y</sup>	0.562
Christianity	19 (7.5)	236 (92.5)	255 (94.4)		
Traditional	0 (0.0)	2 (100.0)	2 (0.7)		
Educational status					
None	0 (0.0)	2 (100.0)	2 (0.7)	1.000 <sup>Y</sup>	0.801
Primary	1 (11.1)	8 (88.9)	9 (3.3)		
Secondary	5 (8.9)	51 (91.1)	56 (20.7)		
Tertiary	14 (6.9)	189 (93.1)	203 (75.2)		
Occupation					
Housewife	1 (2.9)	34 (97.1)	35 (13.0)	1.138 <sup>Y</sup>	0.951
Business	8 (8.7)	84 (91.3)	92 (34.1)		
Professional	11 (9.4)	106 (90.6)	117 (43.3)		
Artisan	0 (0.0)	8 (100.0)	8 (3.0)		
Student	0 (0.0)	11 (100.0)	11 (4.1)		
Others	0 (0.0)	7 (100.0)	7 (2.6)		
Social class					
Upper	4 (5.6)	67 (94.4)	71 (26.3)	1.113	0.573
Middle	8 (6.8)	110 (93.2)	118 (43.7)		
Lower	8 (9.9)	73 (90.1)	81 (30.0)		

$\chi^2$ : Chi square; <sup>Y</sup>: Yates Corrected Chi square; \*: P value <0.05 (i.e. statistically significant)

**Table 2: Risk factors in women diagnosed with hyperglycemia before 24 weeks**

	Hyperglycemia		Total <i>n</i> (%)	$\chi^2$	<i>P</i>
	Present <i>n</i> (%)	Absent <i>n</i> (%)			
Gravidity					
1	5 (6.8)	68 (93.2)	73	0.067	0.967
2-4	14 (7.7)	168 (92.3)	182		
> 4	1 (6.7)	14 (93.3)	15		
Previous Delivery of a macrosomic baby				30.331 <sup>Y</sup>	<0.001*
Yes	6 (54.5)	5 (45.5)	11		
No	14 (5.4)	245 (94.6)	259		
Previous fetal death in utero				2.784 <sup>Y</sup>	0.095
Yes	3 (23.1)	10 (76.9)	13		
No	17 (6.6)	240 (93.4)	257		
Previous still birth				1.985 <sup>Y</sup>	0.159
Yes	3 (20.0)	12 (80.0)	15		
No	17 (6.7)	238 (93.3)	255		
Previous baby with congenital malformation				0.909 <sup>Y</sup>	0.340
Yes	0 (0.0)	2 (100.0)	2		
No	20 (7.5)	248 (92.5)	268		
Previous spontaneous miscarriage				0.106	0.745
Yes	5 (6.6)	71 (93.4)	76		
No	15 (7.7)	179 (92.3)	194		
History of spontaneous recurrent miscarriage				2.060 <sup>Y</sup>	0.151
Yes	2 (28.6)	5 (71.4)	7		
No	18 (6.8)	245 (93.2)	263		
First degree relative with diabetes				30.641 <sup>Y</sup>	<0.001*
Yes	8 (42.1)	11 (57.9)	19		
No	12 (4.8)	239 (95.2)	251		
BMI				30.331 <sup>Y</sup>	<0.001*
Obese	6 (54.5)	5 (45.5)	11		
Non obese	14 (5.4)	245 (94.6)	259		

$\chi^2$ : Chi square; Y: Yates Corrected Chi square; \*: *P* value <0.05 (i.e. statistically significant)

**Table 3: Evaluation of diagnostic performance of Random Plasma Glucose and Random Capillary Glucose in detecting hyperglycemia in early pregnancy**

Evaluation	Random Plasma	Random
	Glucose	Capillary Glucose
Sensitivity	30.0%	40.0%
Specificity	97.2%	92.4%
Positive predictive value	46.2%	29.6%
Negative predictive value	94.6%	95.1%
False positive	2.8%	7.6%
False negative	70.0%	60.0%
Accuracy	92.2%	88.5%
AUC (95%CI)	0.72 (0.66-0.77)	0.69 (0.63-0.75)

AUC: area under curve, CI: confidence interval

Previous delivery of a macrosomic baby, history of diabetes in first degree relatives and maternal obesity were statistically significant risk factors for hyperglycemia in the respondents, each with a *P* value less than 0.05 as shown in Table 2.

The diagnostic performance of random plasma glucose and random capillary glucose against 75g OGTT done before 24 weeks is shown in Table 3. This showed low sensitivities (30% RPG, 40%RCG) for both screening tests, but high specificities (97.2% RPG, 92.4% RCG) with RPG performing better than RCG with accuracy of 92.2%.

Table 3 also shows the receiver operating characteristic of RPG and RCG in relation to hyperglycemia diagnosed with 75G OGTT. The best threshold for screening according to this study was 5.4 mmol/L for RPG and 5.7 mmol/L for RCG both with a sensitivity of 45% and a specificity of 90.0%. The area under the curve (AUC) for RPG was 0.72 (fairly accurate) while that for RCG was 0.69 (poorly accurate) in diagnosing hyperglycemia of early pregnancy. The diagnostic performance of the new cut off values for random plasma glucose and random capillary glucose in detecting hyperglycemia in early pregnancy were also determined. The sensitivities of the

**Table 4: Predictors of elevated hyperglycemia in early pregnancy**

Variables	75-g OGTT fasting				75-g OGTT 1hr				75-g OGTT 2hr			
	$\beta$	P	95%CI		$\beta$	P	95%CI		$\beta$	P	95%CI	
			lower	upper			lower	upper			lower	upper
DM in 1st Degree Relatives	0.160	<0.001*	0.197	0.987	0.146	0.02*	0.164	1.578	0.182	0.02*	0.369	1.639
Previous History of Spontaneous Miscarriage	0.023	0.64	-1.59	0.257	-0.004	0.95	-0.385	0.359	0.006	0.91	-0.315	0.354
Previous History of IUFD	0.40	0.44	-2.71	0.622	0.41	0.48	-0.510	1.089	0.134	0.02*	0.163	1.600
Previous History of Macrosomia	-0.377	<0.001*	-0.762	-0.364	0.107	0.16	-0.099	-0.612	-0.036	0.62	-0.400	-0.239
RPG	-0.280	<0.001*	-1.711	-0.604	-0.269	<0.001*	-2.675	-0.905	-0.262	<0.001*	-2.434	-0.791
RCG	-0.103	0.13	-0.774	0.102	-0.138	0.43	-1.424	-0.024	-0.134	0.05	-1.300	-0.002

Level of significance at  $P < 0.05$ ,  $\beta$ : regression coefficient, CI: confidence interval, IUFD: intrauterine fetal death, RPG: random plasma glucose, RCG: random capillary glucose

new cut off values were 45%, specificity of RPG (90%) is slightly higher than that of RCG (86.8%), while the accuracy of both are above 80%.

Table 4 shows predictors of hyperglycemia in early pregnancy using multiple regression analysis. History of diabetes in first degree relatives and elevated RPG showed statistical significant association with the three components of 75-g OGTT.

## DISCUSSION

The prevalence of hyperglycemia in early pregnancy in this study was 7.4% based of 75g OGTT. This lies within the globally quoted prevalence range of 1-20%,<sup>[17-19]</sup> with that of Olagbuji *et al.*<sup>[14]</sup> (8.6%) inclusive. There is an increasing evidence that prevalence of hyperglycemia first diagnosed in pregnancy is rising globally.

The mean age of the study participants was  $30.41 \pm 4.69$  years with a range of 18-43 years. Majority of the respondents were Christians and of Yoruba ethnicity. This is a reflection of the study location of Ekiti State in western Nigeria. Ekiti state is also predominantly populated by civil servants, this may be the reason why majority (43.7%) belonged to the middle socio-economic class. More than seventy percent (75.2%) of the study participants had tertiary education while the average gestational age at recruitment was  $19 \pm 3.39$  weeks with 67.4% being multigravidas.

The study was unable to find any significant relationship between hyperglycemia and socio-demographic characteristics like marital status, ethnic group, religion

and educational status. This is similar with the reports by Kuti *et al.* and Anzaku *et al.*<sup>[20,21]</sup>

A total of 20 women were diagnosed with hyperglycemia before 24 weeks using 75g OGTT. Previous history of delivery of a baby with macrosomia, first degree relative with diabetes and maternal obesity were found to have significant association with hyperglycemia. This is consistent with the findings of previous studies.<sup>[16,21,22]</sup> This study however was not able to prove any significant association between hyperglycemia in early pregnancy and gravidity, unexplained IUFD, previous fetal congenital anomaly and spontaneous miscarriage, this was still in keeping with the findings of Anzaku *et al.*<sup>[20]</sup>

While setting the cut off value for both RPG and RCG at 5.8 mmol/L,<sup>[13]</sup> this study found out that both screening tests had low sensitivities (30% and 40% respectively) but high specificities (97.2% and 92.4%, respectively), meaning they may not be the best tests for screening of hyperglycemia, but may however be very useful tool for confirming hyperglycemia due to their high specificities. Overall, RPG performed better than RCG with accuracy of 92.2% compared to 88.5% for RCG. These findings were at variance with those of Meek CL *et al.*<sup>[23]</sup> and Church D *et al.*<sup>[24]</sup>. Meek CL *et al.* found a higher sensitivity (70%) but similar specificity (90%), while Church D *et al.* also reported a higher sensitivity (78%) but a lower specificity (85%). These differences may be due to the variation in the cut off values used. Meek CL *et al.* used 7.5 mmol/L, while Church D *et al.* used 7.0 mmol/L in their studies.

The diagnostic performance of random capillary glucose in this study was similar to that found by Fadl H *et al.*<sup>[11]</sup> who while setting RCG cut off at 5.0 mmol/L reported a sensitivity of 47% and specificity of 96%. This however is at variance with the findings of Suresh BG *et al.*<sup>[25]</sup> who reported RCG sensitivity of 100% and specificity of 98.8% at cut off of 7.78 mmol/L.

This study tested for the accuracy of RPG and RCG in detecting hyperglycemia in early pregnancy by plotting ROC curve. This showed that RPG was fairly accurate with an area under the curve (AUC) of 0.72 and performed better than RCG with AUC of 0.69. This finding was similar to that of Mohan V *et al.*<sup>[9]</sup> who found AUC of 0.73 for RPG, but lower than 0.81 by Meek CL *et al.*<sup>[23]</sup>. The AUC of 0.99 for RCG found by Suresh BG *et al.*<sup>[25]</sup> was higher than that recorded in this study. This can be explained due to the difference in the cut off values and variation in the study population.

Based on the findings from this study, a threshold for diagnosis using RPG and RCG were determined to be 5.4 mmol/L and 5.7 mmol/L respectively. This is due to their higher sensitivities of 45% while specificity for RPG was 90% and RCG 86.8% in the study population. These two new cut off values detected 9 cases of hyperglycemia in the study respondents and there was statistical significance between them and 75g OGTT ( $P < 0.001$ ). Other studies<sup>[23,24]</sup> had established the best thresholds to be between 7.31-7.40 mmol/L. The variation may be related to the characteristics of the study population including dietary variation.

Evaluating the diagnostic performance of these new cut off values of RPG and RCG gave a specificity of 90% and 86.8% with accuracy of 86.7% and 83.7% respectively. The low sensitivities (RPG 45%, RCG 45%) and the high false negative values (RPG 55%, RCG 55%) may be connected with the fact that insulin resistance increases as pregnancy progresses but these are done at gestational age less than 24 weeks.

The low sensitivity and high false negative rates found in this study made universal screening of all pregnant women with RPG or RCG before 24 weeks unjustified. It is however quite informative that 20 out of 270 women screened were diagnosed with hyperglycemia in early pregnancy. Likewise based on the knowledge that the impact of glycemic control on pregnancy outcome is related to the period of gestation at first diagnosis, these may make case for early screening in women with family history of diabetes, maternal obesity or history of previous macrosomic babies. When random blood glucose is considered for screening, RPG before 24 weeks should be preferred since it performed better

than RCG and those screened positive made to proceed for 75g OGTT though this is not cost effective. Using the fasting plasma glucose component of OGTT for screening will probably be more cost effective. Those screened negative can then be re-screened between 24-28 weeks of gestation.

This prospective cross-sectional study was limited by the fact that it was carried out in just two teaching hospitals in Ekiti State. The need to schedule multiple visits for sample collection served as a major limitation as some patients never presented for OGTT. Also the period of fasting before 75g OGTT was subjectively reported by the respondents, and there was no means to verify such. There were also few studies on universal 2 steps screening and diagnosis of hyperglycemia in early pregnancy using RPG or RCG and 75g OGTT with which this study can be compared.

Findings from this study established the fact that both RPG and RCG performed poorly across the accuracy measures investigated in detecting hyperglycemia in early pregnancy relative to IADPSG diagnostic criteria based on 75-g OGTT.

This study established that both RPG and RCG performed poorly compared to 75-g OGTT in screening for hyperglycemia in early pregnancy, it is however important to note that the negative predictive values of both screening tests in prediction of hyperglycemia in early pregnancy in this study was high 94.6-95.1%. This may suggest that even though elevated RPG and RCG do not have enough sensitivity to detect hyperglycemia before 24 weeks, the findings of normal values suggests it is unlikely that a woman will develop hyperglycemia in early pregnancy.

All women who screened negative for hyperglycemia before 24 weeks should have a repeat screening and diagnosis with 75g OGTT between 24-28 weeks, and a study comparing screening before 24 weeks and between 24 and 28 weeks is needed to confirm the findings from this study.

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### Declaration of patient consent

The authors certify that they have obtained appropriate patient consent forms. In the forms, the patients gave their consents for their clinical information to be reported in this journal. The patients understand that their names and initials will not be published and due efforts will be

made to conceal their identity but anonymity cannot be guaranteed.

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### Conflicts of interest

There are no conflicts of interest.

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