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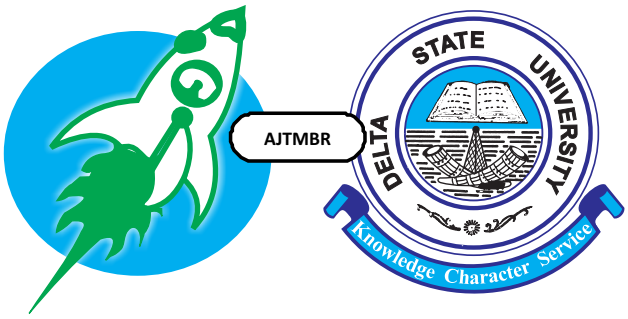

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Focus and Scope

The African Journal of Tropical Medicine and Biomedical Research is a multidisciplinary and international journal published by the College of Health Sciences, Delta State University of Abraka, Nigeria. It provides a forum for Authors working in Africa to share their research findings on all aspects of Tropical Medicine and Biomedical Sciences and to disseminate innovative, relevant and useful information on tropical medicine and biomedical sciences throughout the continent. The journal will publish original research articles, reviews, editorials, commentaries, short reports, case reports and letters to the editor. Articles are welcome in all branches of medicine and dentistry including basic sciences (Anatomy, Biochemistry, Physiology, Pharmacology, Psychology, Nursing etc) and clinical sciences (Internal Medicine, Surgery, Obstetrics and Gynaecology, Dental surgery, Child Health, Laboratory Sciences, Radiology, Community Medicine, etc). Articles are also welcome from social science researchers that document the intermediating and background social factors influencing health in countries of Africa. Priority will be given to publication of articles that describe the application of the principles of primary health care in the prevention and treatment of diseases.

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Prevalence of gestational diabetes mellitus, fetal and maternal outcomes of parturients with risk factors versus parturients without risk factors for gestational diabetes mellitus: A preliminary analysis of the comparative study of blood sugar levels at a tertiary hospital in southern Nigeria

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Abstract

Background: Typically asymptomatic, gestational diabetes mellitus (GDM) has been associated with myriads of maternal and fetal complications and has been shown to predict morbidity in both mother and the newborn much later in life. The incidence of these complications in GDM has been strongly associated with a maternal glycemic level. As a generalization, the degree of maternal hyperglycemia dictates the fetal outcome.

Methods: This study was a prospective cohort analytical observational study of blood glucose levels amongst two cohorts of women who attended antenatal care at the obstetric unit of Delta State University Teaching Hospital, Oghara.

Results: The prevalence of GDM was 31.3% and 9.4%, respectively, for cases and controls. The difference in prevalence and glycemic control was statistically significant. The subjects were recruited based on a positive history of - previously haven had macrosomic babies, maternal weight greater than 90kg, unexplained intrauterine fetal death/stillbirth, fasting glycosuria, and the presence of a family history of GDM in first-degree relatives. Interventional deliveries and maternal and fetal complications were statistically significantly higher in cases than in controls.

Discussion: The prevalence of GDM in cases was significantly higher than in the controls; this seems to have given some credence to the fact that the risk factors based on which the patients were recruited may indeed be predictive of the risk of developing GDM in the pregnant parturients in Delta State Nigeria.

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Introduction

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance of variable severity with onset or first recognition during pregnancy[1-5]. Undoubtedly, some women with gestational diabetes have previously unrecognized overt diabetes. Incidence of GDM depends on the population studied and the diagnostic criteria employed[6] but is said to affect about 3-10% of pregnancies generally and accounts for 90% of diabetes mellitus in pregnancy [4,7]. GDM is pregnancy-induced, and it

occurs when the β-cell reserve cannot counter-balance the insulin resistance caused by placental hormones [6,8].

Even though various diagnostic criteria which predict adverse pregnancy outcomes exist[9,10], diagnosis of GDM is based on World Health Organization (WHO) criteria for Glucose tolerance based on a 75 g -oral glucose tolerance test (OGTT):

> Normal glucose tolerance: *Fasting plasma glucose <7.0 mmol/l; 2hrs after 75g oral glucose load <7.8 mmol/l*
> Impaired glucose tolerance: *Fasting plasma glucose <7.0 mmol/l; 2hrs after 75g oral glucose load >7.8 - <11.1 mmol/l*
> Diabetes: *Fasting plasma glucose >7.0 mmol/l; 2 hrs after 75g oral glucose load >11.1 mmol/l*

Although many studies have lent credence to the benefit of screening, there is no consensus on the timing of the screening, but it is usually done at 24-28 weeks[11].

Though typically asymptomatic, GDM has been associated with myriads of maternal and fetal complications and has been shown to predict morbidity in both mother and the newborn much later in life. The incidence of these complications in GDM has been strongly associated with a maternal glycemic level, and as a generalization, it is the degree of maternal hyperglycemia that dictates fetal outcome[6,8]. Fetal complications include congenital abnormalities, stillbirth, macrosomia, increased risk of birth trauma, neonatal hyperbilirubinemia, neonatal hypoglycemia, and long-term complications like childhood obesity and type II DM in the offspring[4,5,8,8,12]. Maternal complications include increased risk of preeclampsia, obstructed labor as a result of macrosomia, increased risk of operative deliveries; shoulder dystocia, genital track injuries, and development of type II DM later in life with more than half of women with gestational diabetes ultimately developing overt diabetes in the ensuing 20 years[1,5,13]

Overall, reductions in perinatal complications among women actively treated for GDM have been demonstrated in several studies. These include an Australian randomized clinical trial that demonstrated better perinatal outcomes in the intervention (with diet or insulin) group[14]; and an analysis of the effects of carbohydrate-restricted diet in patients with diet-controlled Gestational Diabetes in California, USA which demonstrated an improved glycemic control, less need for insulin therapy, decrease in the incidence of large for gestational age infant, and a decreased in cesarean deliveries for cephalo-pelvic disproportion (CPD) and macrosomia[15].

Therefore, the ability to recognize parturients at risk, promptly diagnose the disorder through screening, and institute appropriate management will avert many of these complications.

Studies have linked GDM with various risk factors which predict the occurrence of the disease[16], though about 40-60% of cases have no risk factors. These established Risk factors for GDM are Body mass index >30 kg/m2, Age>25 years old, GDM in a previous pregnancy, Family history of diabetes, Previous delivery of a large baby, and Previous stillbirth. Whereas previous studies[17] had sought to identify the presence of risk factors in parturients already independently recruited into such studies evaluating GDM, we, however, believe that using identified risk factors as a basis *ab initio* for recruiting our cases and the absence of any such risk factors for controls, may help to authenticate in our population the validity of these factors being predictive of developing GDM. This is against the background of our low

resources settings, where resources may be unable to support routine screening for all our pregnant population. We believe that the outcomes of this study could serve as a basis to design relevant interventions, including public health-related advocacy activities that would help optimize the health outcomes of pregnant women and their babies, thereby helping to achieve the maternal and perinatal global targets of the sustainable development goals.

It is against this backdrop that this study was conceptualized to determine the incidence of GDM in the women seen at the antenatal clinic of Delta State University Teaching Hospital if significant differences existed in the glycemic levels and in the maternal and fetal outcomes among parturients who have antenatal risk factors for GDM and parturients who have no antenatal risk factors for GDM.

Methods

This study was a prospective cohort analytical observational study of blood glucose levels amongst two cohorts of women who attended antenatal care at the obstetric unit of Delta State University Teaching Hospital, Oghara. The first cohort (cases) were women with proven risk factors for GDM, while the second cohort of women (control) were those without risk factors for GDM. Any parturient with one or more of these established risk factors for the development of Diabetes mellitus: *Previous history of macrosomic (>4kg) babies, Maternal weight >90kg; Previous unexplained intrauterine fetal death/stillbirth; Previous congenital malformation; Fasting glycosuria on two occasions; and Family history of GDM in any 1st-degree relative was recruited as a case upon given informed consent.* For every recruited patient with risk factors for GDM, the next presenting patient to the antenatal clinic matched for Age, height, and gestational Age of the pregnancy without any of the established predisposing risk factors for GDM were recruited as controls. Both groups of parturients underwent glucose screening during pregnancy between 24 to 28 weeks and were followed up to establish the maternal and fetal outcomes when they presented in labor.

There was a liaison with the DELSUTH laboratory unit that ensured quality control in the analysis of blood samples for glucose levels.

The authors bore the cost of screening the parturients with risk factors for GDM (cases) and the cost of screening parturients without antenatal risk factors for GDM (controls).

Ethical clearance was sought and obtained from DELSUTH Ethical Committee. Informed consent was obtained from all the parturients recruited into the study. Those who declined consent were excluded from the study.

The sample size was calculated using the formula: $n = (Z^2 \times PQ)/ d2$, and the expected figure was obtained using a degree of accuracy of 5% with a confidence interval of 95%. The power of analysis was based on a previous study with a prevalence of gestational diabetes of 6.8%.[18,19] Where n = desired minimum size; Z = score for a confidence interval of 95%, which is 1.96; P = proportion of women with gestational diabetes mellitus from the previous study is 6.8%; Q = complementary proportion equivalent to one (1) minus P, Q = 1- 0.068=0.932; and d = degree of accuracy desired which is 5% = 0.05. Therefore, n = 97.4. We assumed an attrition rate of 10%, giving a computed minimum sample size of 108 pregnant women. Thus, 108 parturients with risk factors for GDM and 108 parturients without risk factors for GDM (a total of two hundred and sixteen parturients) would be selected for this study from among parturients presenting for antenatal care at the DELSUTH, Oghara. Thus

far, we have recruited 32 cases and 32 controls. Selected patients were informed and counseled about the study, and only those who gave written consent were enrolled.

A datasheet designed for this study was employed to collect information about each parturient. The variables that were retrieved and entered into the data forms are *the Sociodemographic profile: (Names, Hospital No, Age (yrs), Parity, Level of Education (either None, Primary, Secondary, or Tertiary); Husband's occupation; Vital signs (Weight, Height, BMI, BP); Booking status: (Booked or Un-booked); Risk factors for the development of Diabetes mellitus, Previous history of macrosomic (>4kg) babies, Maternal weight >90kg; Previous unexplained intrauterine fetal death/stillbirth; Previous congenital malformation; Fasting glycosuria on two occasions; and Family history of GDM in any 1st degree relative*.

Between 24 weeks and 28 weeks gestation, glucose screening was conducted for each enrolled parturient. Following an 8-14 hours overnight fast, 5ml of venous blood was collected from each parturient's forearms into a Fluoride oxalate bottle after the patient was requested to drink a 75g of glucose in 100 ml of water over 5-10 mins, and 5 ml of venous blood sample was again collected from the forearm after 2 hrs. Samples were immediately sent to the laboratory for analysis. Results of the Blood sugar were obtained and entered into each parturient's data sheets. The categories of sugar pattern for this study on OGTT were:

Normal <7.0 mmol/l
Impaired glucose tolerance >7.0 <11.1 mmol/l
Diabetic >11.1 mmol/l

The above is based on World Health Organization (WHO) criteria for Glucose tolerance based on a 75 g -oral glucose tolerance test (OGTT):

Normal glucose tolerance: *Fasting plasma glucose <7.0 mmol/l; 2hrs after 75g oral glucose load <7.8 mmol/l*
Impaired glucose tolerance: *Fasting plasma glucose <7.0 mmol/l; 2hrs after 75g oral glucose load >7.8 - <11.1 mmol/l*
Diabetes: *Fasting plasma glucose >7.0 mmol/l; 2 hrs after 75g oral glucose load >11.1 mmol/l*

The parturients with results consistent with impaired glucose tolerance and with frankly diabetic values were grouped in line with the standard definition of GDM. All parturients diagnosed with GDM were commenced on immediate treatment and were co-managed with the endocrine Physician.

All Parturients were followed up from when they presented in labor. After delivery, information on maternal and neonatal outcomes was obtained from the mother's case note and the baby's record and entered into the datasheet. This information was *Mode of delivery (SVD, Forceps, Vacuum, or CS), a complication of delivery, EBL, Live birth or Stillbirth (FSB or MSB), Gestational Age @ delivery, birth weight, APGAR score in 5 minutes, Fetal complications*.

Data captured on the data sheets from all the 64 participants so far was collated, coded, and entered into the computer using Statistical Package for Social Sciences (SPSS PC+), and data was then analyzed with univariate and bivariate statistics using the same SPSS PC+. Differences in rates of outcomes between the two cohorts of parturients were compared using the Chi-square test with Yates correction, as appropriate and relevant deductions were made. The level of significance was set at a P value <0.05.

Results

Overall, 64 booked parturients have been

evaluated, with 32 each as cases and controls, respectively. The Average Age of the parturients (cases and controls) was 33.00 (3.586-3.928), average height was 1.7 (0901-0973), and average gestational at delivery was 38.25 (0.463-0.886). These average parameters were the same in cases and controls as they were matched. The tables and associated explanatory text below present the other findings and outcomes.

Analysis of the sociodemographic variables (table 1) shows that the majority (87.5%) of the respondents had secondary (50%) and tertiary (37.5%) levels of education. Fifty percent of the cases were married to skilled personnel as their husbands, 50% of the controls, on the other hand, were married to professionals as their husbands, and 37.5% were skilled workers. The differences observed were not statistically significant.

The prevalence of GDM between 24 weeks and 28 weeks (table 2) was 31.3% and 9.4%, respectively, for cases and controls. The difference in prevalence and glycemic control was statistically significant.

The analysis of the history of identified risk factors for GDM based on which the cases were recruited (table 3) revealed that fifty percent (16/32) of the cases had a positive history of previous macrosomic babies. The other risk factors that served as a basis for recruiting the study participants were maternal weight greater than 90kg, unexplained intrauterine fetal death/stillbirth, fasting glycosuria, and the presence of a family history of GDM in first-degree relative being the basis of recruitment. The controls were recruited from amongst the parturients without these risk factors.

Table 1: Sociodemographic Characteristics

Parameter	Cases n (%)	Controls n (%)	p-value
Level of education			
None	0	0	
Primary	4 (12.5)	4 (12.5)	NS
Secondary	16 (50)	16 (50)	
Tertiary	12 (37.5)	12 (37.5)	
Husband's occupation,			
Unskilled	8 (25)	4 (12.5)	
Skilled	16 (50)	12 (37.5)	0.1017
Professional	8 (25)	16 (50)	
Average Parity	3.13 (1.126)	2.75 (1.035)	1.000
Average maternal Weight	77.88 (9.687)	68.00 (5.014)	0.023
Total	**32**	**32**	

Table 2: Pattern of blood sugar and the prevalence of GDM

Parameter	Cases n (%)	Controls n (%)	p-value
OGTT @ **24-28 weeks**			
<7.0 mmol/l	19 (59.4)	28 (87.5)	
>7.0 <11.1 mmol/l	3 (9.3)	1 (3.1)	0.0389
>11.1 mmol/	10 (31.3)	3 ((9.4)	

Fifty percent of the cases (parturients with risk factors for GDM) had spontaneous vaginal delivery (SVD). In contrast, 12.5% (4/32) had forceps delivery, and 37.5% (12/32) had cesarean sections - 4 were elective cases on account of identified fetal macrosomia at term, 25% (8/32) were emergency cases with 15.6% (5/32) of the cases due to fetal distress and another 9.4% (3/32) due to fetopelvic disproportion in labor (table 4). Twenty-nine controls (90.6%) had SVD, and only two controls had cesarean sections, which were done as emergencies on account of fetal distress before full cervical dilatation. Eight (12.5%) of the parturients with risk factors for GDM suffered complications, and of these, 5 (15.6%) had genital tract lacerations, and 6 (18.8) had postpartum hemorrhage (PPH). Only one of the controls had complications of PPH. The differences in the complication rates between the cases and controls were statistically significant. Twelve (37.5%) cases had blood loss less than 500mls, and twenty (62.5%) had blood loss greater than 500mls. Only one of the controls had blood loss greater than 500mls. The differences between cases and controls are statistically significant.

All babies were live birth in cases and controls (table 5). However, over half (56.2%) of the babies of parturients with risk factors for GDM had complications, while only 1 (3.1%) of babies in the control arm had complications. Over half (55.6%) of the babies that had complications had birth trauma, 38.9% (7/18) suffered hypoglycemia within the first hour of birth requiring correction by the neonatologists, and one baby had a femoral fracture following a difficult vaginal delivery. The baby in the control arm that had complications suffered birth trauma. The differences between cases and controls were statistically significant (p-values <0.05).

Discussion

This report presents a preliminary analysis of the ongoing study amongst two cohorts of parturients recruited as cases and controls based on a positive or negative history of one or more of the traditionally identified risk factors for developing GDM. Of the six leading established risk factors[16] that served as the basis for recruiting parturients as cases and the absence of which they were classified as controls, family history in first-degree relative (68.7%), previous history of macrosomic babies (50%), fasting glycosuria on two occasions (56.2%), maternal weight >90kg (37.5%) and previous unexplained intrauterine fetal death/stillbirth (25%) were the risk factors volunteered by the parturients in the order of frequency as enunciated. This finding is in keeping with the results of previous studies[16,19-23], in which these factors were identified to increase the risk of developing GDM. In this study, positive history of previous congenital malformation was not reported; however, earlier reports[16,20-23] had indicated it to be associated with an increased incidence of GDM. The Average Age of the parturient in this study was 33.00 ($\pm$3.586-3.928), and existing data[21,22,24,25] suggest an increasing incidence of GDM after the Age of 25 years, with an incidence as high as 11.3% in parturients in the 30-39 age bracket.[21,25]

The overall incidence of gestational diabetes in this preliminary data was 26.7%, the incidence in the cases was 40.6%, and in the controls, it was 12.5%. A huge systematic review and meta-analysis of the prevalence and determinants of gestational diabetes mellitus in Nigeria in 2021 by Azeez et al. revealed that the prevalence of GDM in Nigeria was 0.5-38%.[17] The cohort of women with risk factors for GDM (cases) in our ongoing series had a significantly higher incidence than the controls (p-value =0.0389). This pattern gives credence to the fact that these established risk factors may be predictive of GDM in our

Table 3: Quantification of the History of Risks factors used for recruiting the cases

Parameter	Cases n (%)
Previous history of macrosomic (>4kg)	
Yes	16 (50)
No	16 (50)
Maternal weight >90kg	
Yes	12 (37.5)
No	20 (62.5)
Previous unexplained intrauterine fetal death/stillbirth	
Yes	8 (25)
No	24 (75)
Previous congenital malformation	
Yes	0
No	32 (100)
Fasting glycosuria on two occasions	
Yes	18 (56.2)
No	14 (43.8)
Family history in 1st degree relative	
Yes	22 (68.7)
No	10 (31.3)
Total	32

population, particularly against the backdrop that the incidence reported in the controls is consistent with the national average prevalence rate of 10-15% for the general antenatal population recruited without recourse to the presence of identified risk factors for GDM.[17,26] This report further reveals that a significant proportion of parturients with GDM have no known established risk factors - 12.5% of controls in this study. Evidence[16,20,22,27,28] from previously available data is in tandem with this observation, as about 40-60% of parturients from the earlier reports have no risk factors. This underscores the very critical question Moses et al.[29] raised in their seminal publication, whose title is the question: *Gestational Diabetes: Do all women need to be tested?* We hope to attempt to provide a response to this question at the end of this study when putting together the final report.

Interventional deliveries and adverse maternal outcomes were significantly more prevalent in the cases than controls. This compares favorably with the findings of previous studies.[19] The significantly higher incidence of cesarean sections and operative vaginal deliveries (forceps) associated with the cases compared with controls is consistent with previous reports.[19] Similarly, the cesarean sections' indications compare favorably with earlier reports.[19] Similarly, postpartum hemorrhage was significantly higher in the cases than in the controls.

One striking feature regarding complications was that the rates of maternal and neonatal complications were higher in the cases arm compared to the control arm despite the prompt commencement of all diagnosed with GDM on immediate treatment. This is at variance with the recent (May 2023) report of Simmons et al. in the New England Journal of Medicine[30], in which they showed that there was a modest reduction in some of the composite complication rates and no material differences in some other complications rates in the neonates in the group that was commenced on immediate treatment as compared with those that had no immediate treatment. Additionally, in the ACHOIS study,[31] the composite endpoint (neonatal death, perinatal injury, hyperbilirubinemia, neonatal hypoglycemia, and hyperinsulinemia) was significantly reduced with antihyperglycemic intervention, and there was also a lower weight gain (by 1.7 kg on average) and a lower incidence of LGA. This is instructive, and its implication for this ongoing study is that the treatment regime and compliance, particularly amongst parturients on treatment, needs to be closely monitored and appraised regularly as the survey progresses.

To further buttress the need to monitor and evaluate our treatment and management of parturients diagnosed with GDM for compliance, the fact that the neonates of the parturients that had risk factors for GDM had a significantly higher average birth weight (macrosomia) compared with the neonates of the controls (p-value = 0.000). Fetal macrosomia results from maternal hyperglycemia, which translates to the fetus having higher blood glucose levels and subsequent hyper-insulinemia that increases fetal body weight.[17,32] Fetal macrosomia is largely reflected in a higher incidence of complications in the newborns of diabetic mothers, as aptly seen with the fetal complications in this study, with 56.2% of neonates of cases having one form of complication or the other. In contrast, only 3.1% of neonates suffered complications in the controls. This is also the trend and pattern seen in reports of previous studies.[32]

Both cases and controls showed similar average gestational Age at delivery. This agrees with other authors' findings, which showed that the average gestational age at delivery was similar in both parturients with GDM and no GDM.[30]

Thus far in this study, the estimation of the prevalence rates in cases and controls was significantly higher in cases compared to the controls, and this seems to have given some credence to the fact that the risk factors based on which the cases were recruited may indeed be predictive of the risk of developing GDM in the pregnant parturients in Delta State Nigeria. It does appear that some complications still occurred even though parturients diagnosed with GDM were commenced on medications. This calls for close monitoring and evaluation of our treatment regimen and compliance with prescribed medications and other ancillary treatment modalities to achieve the pattern described in earlier reports.[14,15] We will follow up with a more detailed and comprehensive report after the ongoing study.

Acknowledgment
We like to thank the TET-Fund (Tertiary Education Trust fund) and members of the TET-Fund Research Grant Committee of Delta State University for making available the funds with which this study is being undertaken.
There are, however, no conflicts of interest.

Table 4: Maternal outcomes

Parameter	Cases n (%)	Controls n (%)	p-value
Mode o delivery			
SVD	16 (50)	29 (90.6)	0.0010
Forceps	4 (12.5)	0 (0)	
Vacuum	0	1 (3.1)	
CS	12 (37.5)	2 (6.3)	0.0065
If vaginal delivery, any complication?			
Yes	8 (12.5)	1 (3.1)	0.0309
No	24 (75. 5)	31 (96.9)	
If yes, please specify			
Genital laceration	5 (15.6)	0	
PPH	**6 (18.8)	1 (3.1)	0.0452
If CS, indication (please specify)			
Fetal distress	5 (15.6)	2 (6.25)	0.8442
Fetal macrosomia	4 (12.5)	0	<0.001
Fetopelvic disproportion	3 (9.4)	0	
EBL			
<500ml	12 (37.5)	31 (96.9)	
≥500ml	20 (62.5)	1 (3.1)	0.00001.

**Some cases that had genital tract lacerations also had PPH

Table 5: Fetal outcomes

Parameter	Cases n (%)	Controls n (%)	p-value
Live birth			
Yes	32 (100)	32 (100)	NS
No	0	0	
Stillbirth			
Yes	0	0	
No	32 (100)	32 (100)	NS
Average Gestational age	38.25 (0.886)	38.25 (0.463)	1.000
Average birth weight	4.02 (0.231)	3.44 (0.226)	0.000
APGAR score in 5 mins	9.75 (0.707)	10.00 (0.000)	0.351
Neonatal complications*			
Yes	18 (56.2)	1 (3.1)	
No	14 (43.8)	31 (96.9)	0.00001.
If yes, specify			
Trauma**	10 (55.6)	1 (3.1)	0.0317
Hypoglycemia	7 (38.9)	0	
Fracture	1 (5.5)	0	

*some neonates suffered more than one complication ** Bruises, minor lacerations

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