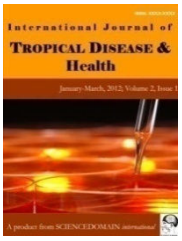

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Gestational Diabetes: Risk Factors, Perinatal Complications and Screening Importance in Niger Delta Region of Nigeria: A Public Health Dilemma

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Research Article

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ABSTRACT

Aim: The study identified the incidence of undiagnosed gestational diabetes and its consequences on maternal/neonatal mortality and highlighted screening importance in an African urban setting in the Niger Delta region in Nigeria.
Study Design: Randomised study.
Place and Duration of Study: Pregnant women attending antenatal clinics in one tertiary, six primary, six secondary, hospitals, and six maternity homes in the Niger delta area of Nigeria between May 2006 to May 2009.
Method: A total of 1920 pregnant women were recruited into the study. While 956 received the oral glucose test and formed the study group, 964 declined from continuing in the study, and formed the control group.
Results: Women with gestational diabetes were at increased risk for premature rupture of membranes, preterm birth; breech presentation and high birth weight adjusting for maternal age.
Conclusion: The presence of gestational diabetes in pregnancy is predictive of poor pregnancy outcome as it remains undetected in conception resulting in unto wards maternal/neonatal complications.

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Keywords: Gestational diabetes; risk factors; antepartum screening.

1. INTRODUCTION

Gestational diabetes mellitus (GDM), defined as carbohydrate intolerance first diagnosed during pregnancy (Moses and Cheung, 2009) is associated with increased risk of fetal malformation and perinatal mortality. Complications of GDM are of varying degrees depending on the clinical attributes and the diagnostic criteria employed. The risk of excessive fetal growth in pregnancies is complicated by gestational diabetes and is a direct result of the multifaceted maternal metabolic anomaly, orchestrated by a steady increase in the maternal glycemic level. Pregnancy is associated with changes in placental lactogens and elevated circulating estrogen and progesterone, which produce a diabeticogenetic state. As a result, insulin and carbohydrate metabolism become altered in order to make glucose more readily available to the fetus. The diminished responsiveness to insulin engenders high postprandial glucose levels that remains raised for longer periods, than in the prepregnant state. Some pregnant mothers who cannot metabolise the excessive glucose end up having GDM, which jeopardises the fetal well being (Berger and Sermer, 2009). Increased risk of fetal malformation and perinatal mortality is likely to be confined to an asymptomatic subgroup of patients with GDM in whom diabetic status is unrecognised before pregnancy (Kozhimannil et al., 2009).

The significance of surveillance for GDM has been questioned because of the lack of consistent evidence on its effect on pregnancy outcomes (Metzger and Coustan, 1998). Although there is evidence that recommended screening protocols for women with GDM, they are not steadfast in this part of the globe, seeing that women at risk for DGM go undetected, which is detrimental to the mother and the unborn child. Preferred screening protocol should identify subjects at maximal risk of adverse pregnancy outcome who would benefit most from intensified management and surveillance, while freeing the rest from the burden of excessive interventions (Metzger et al., 2008). There have been no adequately designed randomised controlled trials to answer the question of whether risk factor screening to rule out or rule in GDM is beneficial and cost effective; which will resolve the long standing variance in screening practices, especially in sub Saharan Africa. Management of a screening-detected population with mild gestational diabetes would reduce serious neonatal (as a composite outcome) and maternal (gestational complications) outcomes (HAPO, 2002) in Niger Delta region. This is a growing community that has begun to witness improved infrastructural advancement and enhanced standard of living due to oil and gas exploration (Appendix I). The citizens are endemic to obesity and predisposing factor for gestational diabetes.

A better understanding of the association between these conditions may lead to more effective strategies for prenatal care and would ultimately allow for a better understanding of their pathophysiology. The recent 'Hyperglycemia and Adverse Pregnancy Outcome (HAPO) (Kwak et al., 2008; HAPO, 2002; Metzger et al., 2008; Lindsay, 2009) study was designed to address the question of whether the risk factor of an adverse outcome for the baby can be related to degrees of maternal glucose intolerance below the established cut-off points for diabetes and has been a yard stick for monitoring patience for diabetes .This study stems from increasing number of prenatal anomalies such as prenatal morbidity and adverse neonatal outcome (fetal macrosomia, neonatal hypoglycaemia, still birth, maternal ketoacidosis, genital injuries during delivery and postpartum haemorrhage), that present

within the patient profile in the community. We therefore, seek to conduct a community based case control study to identify the incidence of undiagnosed GDM and its consequences on maternal and neonatal outcome and highlight screening importance when the condition is not identified in pregnant mothers.

2. MATERIALS AND METHODS

2.1 Study Design

We randomly selected women between 16 and 34 weeks gestation who attended antenatal clinics at the collaborating hospitals and birthing centers, and who had one or more risk factors for gestational diabetes on systemic screening. Screening procedures identify pregnant women who were at sufficient risk to warrant a diagnostic test of oral glucose-tolerance test. Respondents receive a focused group lecture and interview on gestational diabetes. The risks that GDM mothers and their unborn babies were exposed to, if left undetected were elucidated.

2.2 Criteria for Selection

Three thousand and eighty pregnant women attending prenatal clinics and birthing centres were randomly screened at each first antepartum visit.

Pregnant women between 16 and 34 weeks of gestation were screened, those having one or more risk factors for gestational diabetes (Appendix III), were offered the option of taking the 50-g oral glucose challenge test (OGT). A total of 956 randomly screened pregnant women received the oral glucose challenge test; this formed the study group, while 964 of the pregnant women declined from taking the oral glucose challenge test.

Reason for declining to take the glucose challenge test was by choice. They claimed they could not starve overnight, fear of invasive procedures should they test positive with the OGT and concern that it might affect the unborn baby and ignorance were some of their reasons. Their autonomy was respected and they formed the control group. The rest, 1160 women who did not give consent refused to continue with the study with others.

Respondents were provided with written information about the study, before the oral glucose challenge test was administered. Those whose serum glucose concentration at screening was sufficiently high (defined as ≥7.8 mmol/L at 1h) underwent a 75g oral glucose tolerance test (GTT), at 24-34 weeks gestation. Prior to the GTT, they were encouraged to follow a normal 48 hours diet before the oral glucose-tolerance test and to fast for 8 hours the night before the test. Blood samples were obtained after the overnight fast and one and two hours after the receipt of the 75g oral glucose load, in accordance with the world health organisation (WHO), guidelines.

2.3 Interventions

Women who were randomly assigned to the intervention group received ongoing care by the attending obstetrical team with a physicians support. The care of the women in the intervention group replicated clinical care in which universal screening and treatment for gestational diabetes were available, while the care of the women in the routine care group replicated clinical care in which screening for gestational diabetes is not available. At the

discretion of the attending clinician, if indications arose that were suggestive of diabetes, further assessment for gestational diabetes was permitted, with treatment as considered appropriate.

The option of labour induction at earlier gestational age at birth was utilized to prevent maternal/ child complications that was pronounced in the control group. Interventions included individualized dietary advice from a qualified dietician, which took into consideration a woman's' pre-pregnancy weight, activity level, dietary intake and weight gain; instruction (ADA, 2008). Respondents received ongoing care by the attending primary care givers, consisting of obstetrical team with physicians and nurses support. Antepartum management of pregnant women and those with gestational diabetes that focused on the prevention of fetal complications was followed (U.S. Preventive Service Task Force, 2008).

This is in accordance with the American Diabetes Association which recommends the provision of adequate calories and nutrients to meet the needs of pregnancy and to minimize maternal hypo/hyperglycaemia (Moses et al., 2009). Subjects newly diagnosed with GDM were managed conventionally with dietary intervention; only known diabetes and those whose blood glucose levels warranted prophylaxis were placed on insulin, while the control group continued with the normal care.

2.4 Ethical Approval and Consent

Informed consent was obtained and ethical approval was granted for the study.

2.4.1 Data analysis

The investigators developed an analytic framework (Appendix II) that incorporated 4 key questions to guide the study:

Does screening for gestational diabetes lead to a reduction in perinatal morbidity and mortality for mother or infant during the prenatal period until birth?

Does management of gestational diabetes lead to reduction in perinatal morbidity and mortality for mother or infant during the prenatal period until birth?

What are the challenges and potential harm in universal screening for gestational diabetes during the period until birth?

What is the adverse effect associated with screening for gestational diabetes during perinatal period until birth, are there any psychological effect related screening?

2.4.2 Outcome of selective screening surveillance

Using inclusion criteria developed for each key question (described in Appendix II), the investigators assessed the potential benefits of gestational diabetes screening and management in improving final health outcome of the subjects.

2.4.2.1 Key question no.1

Findings from this study indicate that screening and subsequent management in a screened population of women at high-risk for gestational diabetes reduced macrosomia and other

prenatal complications. Also the intervention group gained statistically significantly less weight during pregnancy, than the control group (Table 4). The rate of serious perinatal complications (stillbirth, neonatal death, shoulder dystocia, macrosomia) was lower in infants of the screened population than in the untreated group (Table 2).

2.4.2.2 Key question no. 2

Was designed to determine whether management of gestational diabetes could lead to reduction in perinatal morbidity and mortality for mother or infant during the prenatal period until birth. The gestational diabetics detected in universal screening programs in the intervention group received both individualized dietary advice and instructions to self-monitor glucose levels for new/known diabetics; a beneficial approach that is in line with preventive modalities for perinatal complications. The neonates of women on the intervention group were less likely to have perinatal deaths, hypoglycaemia and respiratory distress from the (5-minutes Apgar score <7) post delivery (Table 2).

2.4.2.3 Key question no. 3

What are the challenges and potential harm in universal screening for gestation diabetes during the prenatal period until birth?

A potential harm of gestational diabetes screening is unnecessary glucose testing and treatment of many women who would not ultimately develop problems related to gestational diabetes. Potential benefits include reduction in maternal premature rupture of membrane, stillbirth, breech presentations and caesarean sections due to macrosomia and other fetal anomalies (Table 2).

2.4.2.4 Key question no. 4

What are the adverse effects associated with screening for gestational diabetes during the perinatal period until birth, are there any psychological effect related universal screening?

Other than the invasive procedure for positive results, the 8 hour postprandial fasting, and fear of harm to the unborn fetus, the investigators found no statistically significant association of anxiety, depression, or concern for the baby's health with glucose challenge test results. However, women from intervention group who had negative results reported more vitality, greater social functioning and were more likely than those with positive results to rate their screening experience as positive. Hence, the researchers found no differences in any other domain.

3. LIMITATION

Several caveats are noteworthy. The investigators believe it is unlikely that a study of this magnitude could ever be conducted in Nigeria, given the level of knowledge deficits relatively common in the populace regarding universal GDM screening and institutionalized ethical constraints for research in human subject.

Access to sites, bad roads, poor transportation facilities to and from healthcare centres and level of illiteracy were some of the limitations we encountered. These were partially overcome by providing a stipend of five hundred naira (equivalent to US$5) to each participant to augment for transportation during each session.

4. RESULTS

A total number of 3080 pregnant women attending prenatal clinics and birthing centres were recruited in the study. A total of 1920(62.33%) respondents met the inclusion criteria, and were included in the follow-up study. Reasons for exclusion were pre-existing medical disorders and incomplete records and refusal to sign the informed consent for the study. Among the 1920 women screened, 956(49.79%) conceded to taking the oral glucose challenge test, these formed the study group, while 964(50.20%) declined from taking the oral glucose challenge test, they formed the control group. In the screened study group, 65(6.8%) of the mothers tested positive for gestational diabetes, including known diabetics. The known diabetics were 17(1.8%) while 48(5%) did not have previous positive diabetic history.

Participants in the intervention group who tested positive were given high risk care because they had the most potential for perinatal complication, while the other received routine-care. Clinical outcomes were obtained up to the time of hospital discharge for all 1920 women and their 1928 infants.

Participants in the study were largely primiparous, with average age of 30 years (Table 1). Maternal/neonatal complications were assessed and recorded. In newborns, anthropometric measurements recorded within 24 hours of birth were Apgar score, birth weight, crown-heel length (CHL), head circumference (HC), chest circumference (CC) and mid arm circumference (MAC). Adverse neonatal outcome assessed and compared were premature birth, meconium aspiration syndrome(MAS), low birth weight, macrosomia, neonatal hyperbilirubinemia and, neonatal birth weight <2500g and >2500g. In the mothers, premature rupture of membrane (P-ROM), breech presentation, induced labor, caesarean section and normal full term delivery (SVD) (Table 2).

Mothers and babies were examined twice daily for development of any complications until they were stabilized while still in the study, and later cleared for discharge. Serious perinatal complications were significantly less frequent in the intervention group than in the routine care group (Table 2). No neonatal demise in the intervention group, but there were deaths in the control group 4(0.41%). More babies were admitted to the neonatal intensive care unit (NICU) from the control group 30(3.1%), than from the intervention group 16(1.7%) (Table 2).

The proportion of infants with jaundice requiring phototherapy in both groups was 9(0.94%) for the intervention group and 13(1.34%) for the control group. Although induced labour ranked more in the intervention group 78(8.16%), and 45(4.66%) for the control group, however, the difference in the rate of caesarean delivery (C/S), was outstanding in the control group. while the intervention group had 7(0.73%) for C/S, the control group had 25(2.59%). Infants born to the intervention group were less likely to be large for their gestational age 2(0.21%) as compared to 20(2.06%) from the control group (Table 2). Table 3 depicts the breakdown of the hospitals, healthcare and birthing centers and size of population served.

Table 1. Clinical screening guidelines and risk factor potentials for GDM possible indicators of early disease N=1920.

Risk factors	Number of women		P value
	Subjects no. (%) N=956	Controls no. (%) N=964	
Age			
≤30	416(43.5%)	468(48.5%)	0.02
31-35	422(44.1%)	358(37.1%)	
≥ 35	118(12.34%)	138(14.3%)	
Body mass index			
≤22	286(30.0%)	334(34.6%)	<0.001
22.1-25	450(47.0%)	418(43.4%)	
≥25.1	220(23.0%)	212(22.0%)	
Parity			
0	431(45.0%)	441(45.7%)	0.01
1	164(17.1%)	176(18.2%)	
2	241(25.5%)	231(24.0%)	
≥3	120(12.5%)	116(12.0%)	
Family history of Diabetes			
Yes	150(15.7%)	160(16.6%)	0.15
No	806(84.3%)	804(83.4%)	
Previous Adverse Obstetrical history			
Yes	169(17.7%)	173(17.8%)	0.03
No	787(82.3%)	791(82.2%)	

Table 2. Maternal/child complications detected from respondent

Maternal complications	**Subject no. (%) N=956**	**Control no. (%) N=964**
Antenatal impatient admissions	12(1.3%)	38(3.9%)
Premature rupture of membranes	16(1.7%)	34(3.5%)
Breech presentation	6(0.6%)	14(1.5%)
Induced labor	78(8.2%)	45(4.7%)
Caesarean section	7(0.7%)	25(2.6%)
Normal full term SVD	837(87.5%)	808(83.8%)
Fetal complications	**Subject no. (%) N=959**	**Control no. (%) N=969**
Macrosomia	2(0.2%)	20(2.1%)
Hypoglycaemia	6(0.6%)	26(2.7%)
5-minutes Apgar score <7	8(0.8%)	41(4.2%)
5-minutes Apgar Score >7	959(99.1%)	828(95.7%)
Jaundice requiring phototherapy	9(0.9%)	13(1.3%)
Respiratory distress syndrome	2(0.2%)	7(0.7%)
Fetal demise	0(0.0%)	4(0.4%)
Polycythemia	1(0.1%)	3(0.3%)
Admission into NICU	16(1.7%)	30(3.1%)
Preterm birth	4(0.4%)	9(1.0%)
Shoulder dystocia/Erbs palsy	0(0.0%)	8(0.8%)
Meconium aspiration syndrome	2(0.2%)	9(0.9%)
Normal full term infant	917(95.6%)	859(88.6%)

Table 3. Breakdown of Hospitals and Healthcare/birthing centres and size of population served

Institutions	Subject no. (%) N=956	Control no. (%) N=964
Tertiary	398(41.6%)	382(39.6%)
Secondary	222(23.2%)	240(24.9%)
Primary	192(20.1%)	204(21.2%)
Birthing centres	144(15.1%)	138(14.3%)
Total	956(100%)	964(100%)

Table 4. Overall weight gain during pregnancy in respondents N=1920

Trimester/Age Variable	Subjects N=582 weight/lb	Control group N=564 weight/lb
First Trimester		
<30	2-3/lb	3-5/lb
31-35	3-4/lb	3-6/lb
>35	2-4/lb	2-5/lb
Second Trimester		
<30	8-12/lb	9-11/lb
31-35	9-12/lb	12-13/lb
>35	10-12/lb	11-14/lb
Third Trimester		
<30	9-12/lb	12-13/lb
31-35	10-12/lb	13-15/lb
>35	11-13/lb	12-15/lb

5. DISCUSSION

In this study while both the intervention group and the control group had some similarities in their risk factor potentials such as BMI, parity and previous obstetrical history (Table 1), which could have reflected similar high maternal risks, however the intervention group had a better positive maternal outcome due to screening and management. This is in line with previous studies that postulated that screening and the management of the population at risk reduces poor pregnancy outcome (Lindsay, 2009; Fraser, 2009; Nelson and Sattar, 2009).

The care of the women in the intervention group is a mirror image of the clinical care in which universal screening and treatment for gestational diabetes are available. Majority of the women in intervention group who tested positive for GDM were asymptomatic prior the glucose tolerance test as the control group. They could have gone unnoticed because selective screening would have failed to detect them.

The inquiry also found no high-quality evidence on sensitivity or specificity of gestational diabetes screening for negative neonatal and maternal outcomes in the intervention group. However, the investigators evidenced that management of a screening- detected population with mild gestational diabetes reduce serious neonatal (as a composite outcome) and maternal (gestational complications) outcomes in this growing community. Prior to the introduction of the current study, women with GDM during pregnancy were unaware of the presence of the conditions and therefore often were being cared for in the same way as

those of their non-GDM counterpart. For instance, during the course of the study, some of the mothers on the control group presented with signs and symptoms of gestational diabetes with the associated complication of macrosomia. They were tested and managed accordingly by their primary healthcare givers as high risk patients.

Fetal macrosomia is a common adverse infant outcome related to GDM, especially if GDM is unrecognized and untreated (Ecker, 2008; Stewart et al., 2009; Walters et al., 2010). Macrosomia and hypoglycaemia were markedly reduced in the intervention group, but was reported with varying frequency in the infants of women in the control group, which might have resulted in the fetal demises in that group, (Table 2).

Infants born to mothers from the intervention group had lower birth weight than those born to women on the control group. This could be explained at least in part by the earlier gestational age at birth in this group, related to the increased use of induction of labor. Infants in the study group were not small for gestational age, neither were they macrosomic. This is consistent with other studies, which postulated that the induction of labor at an earlier gestational age aids in prevention of maternal/child complication (IADP, 2010).

Although some cases in the intervention group had cesarean delivery, the proportion of women who underwent cesarean section was significantly higher in the control group than in the intervention group, which is due to early detection and management of the cases in the intervention group (Table 2). This is consistent with previous studies which proposed that increase rate of cesarean delivery associated with the diagnosis and treatment of gestational diabetes is efficacious (Moses, 2010; Radaelli, 2010).

This study is the first outcome to introduce a universal screening program for pregnancy before symptom presented. In this study, the investigators demonstrated that screening of pregnant women for GDM should not be selective; rather it should be an essential investigations tool for every pregnant woman as in the case of retroviral screening, especially in the sub Saharan region, to eradicate global health inequality.

6. CONCLUSIONS

Universal screening and management of gestational diabetes

- reduces serious perinatal morbidity
- may improve the woman's, health-related quality of life.
- a step towards improved obstetric care in pregnant mothers.
- Prevention of type 2 diabetes in women.
- Prevents childhood obesity of their offspring.

7. RECOMMENDATIONS

If treatment options are to be introduced to women with GDM, universal screening should be favoured for detection of gestational diabetes mellitus. This is in consonance with the International Diabetes Federation new international guidelines which wants all women screened for gestational diabetes with one-step oral glucose tolerance testing which it says should supersede the American Diabetes Association guidelines, which suggests a risk-based screening strategy and, typically, two-step diagnosis.(IDF, 2009).

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX I

Study setting:

The target group of this investigation consisted of pregnant women who were attending antenatal clinics at the collaborating hospitals, prenatal clinics and birthing centres in the Niger delta region of Nigeria. The Niger delta region is a major precinct in the south –south geopolitical zone within Nigeria. It is also among the world's major wetlands; with one of the largest mangrove ecosystems and a major territory of the global diversified industrial activities related to oil and gas exploration. It is the treasure base of the nation, comprising of nine states in the federation, with miscellaneous industrial implementations linked to oil and gas exploration, which attract agglomeration of residents, who are faced with a rising prevalence of gestational diabetes mellitus.

APPENDIX II

Research questions

1. Does screening for gestational diabetes lead to a reduction in perinatal morbidity and mortality for mother or infant during the prenatal period until birth?
2. Does management of gestational diabetes lead to reduction in perinatal morbidity and mortality for mother or infant during the prenatal period until birth?
3. What are the challenges and potential harm in universal screening for gestational diabetes during the prenatal period until birth?
4. What are the adverse effects associated with screening for gestational diabetes during the perinatal period until birth, are there any psychological effects related screening?

APPENDIX III

Risk factor criteria and clinical characteristics for women with potential GDM (one or more of the following)

- Obesity
- Failure to gain weight in pregnancy/maintains pre-pregnancy weight
- Polyhydramnios confirmed by ultrasonic scan
- Glucosuria
- Family history of diabetes
- Diabetes in first degree relative
- Previous adverse obstetrical history
- History of glucose intolerance
- Previous on infant marcrosomia
- Repeated miscarriages without a clear cause
- Repeated still birth without a clear cause