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Research Article

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Performance of Different Glucose Testing Methods Amongst Patients of Gestational Diabetes Mellitus in St. Francis Hospital Nsambya, Kampala, Uganda: A Cross-Sectional and Descriptive Study

Martin Mugenyi[1]*, Esther Muitta[2], Joseph Nyamai Juma[3]

[1]*Department of Medical Laboratory St. Francis Hospital Nsambya, Kampala, Uganda.*

[2]*Department of Medical Laboratory Mount Kenya University, Thika, Kenya.*

[3]*Department of Epidemiology and Biostatistics Mount Kenya University, Thika, Kenya.*

***Corresponding Author**
Martin Mugenyi, *Medical Laboratory St. Francis Hospital Nsambya, Kampala, Uganda.*

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Abstract

Background*: Medical examination detects illness or disease risk factors in individuals otherwise well to treat early on and minimize morbidity and death. In spite of recommended GDM screening during prenatal care worldwide and local standards, it has been shown that the procedure has not been properly implemented. A further difficulty might be the lack of consensus worldwide and on local consistence on GDM screening and diagnosis guidelines.*

Methods*: The study was a hospital based cross-sectional and descriptive study that employed both quantitative and qualitative methods of data collection. A descriptive study was concerned with describing the characteristics of a particular individual, or of a group in a given situation. The study was guided by the primary objective of assessing the extent of GDM monitoring among women receiving antenatal care at St. Francis Hospital Nsambya in Kampala, Uganda. Both Capillary and venous blood samples in which plasma/serum was taken from pregnant mothers and their glucose levels estimated using a One touch (Roche Diagnostics) code 298 and plasma calibrated glucometer and Roche Cobas C311fully automated Chemistry Analyser respectively. Both whole blood glucose and plasma/serum glucose was determined as per the principle of enzyme hexokinase (HK) catalyzes the reaction between glucose and adenosine triphosphate (ATP) to form glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). In the presence of nicotinamide adenine dinucleotide (NAD), G-6-P is oxidized by the enzyme glucose-6-phosphate Dehydrogenase (G-6-PD) to 6-phosphogluconate and reduced nicotinamide adenine dinucleotide (NADH). The increase in NADH concentration was directly proportional to the glucose concentration and was measured spectrophotometrically at 340 nm.*

The data was analysed using the McNemar's test to determine the sensitivity, specificity and the direct cost for performing capillary glucose. Receiver operator characteristic and Area under curve analyses to analyze the predictive power of the constructed equation Sensitivity, specificity, false positive rate and false negative rate was computed to validate the capillary method in testing/detecting Gestational Diabetes Mellitus. Data analysis was performed using the SPSS package

Results*: The results presented below for both capillary and Venous Blood Glucose were based on the principle of glucose oxidase test. Cutoff for the different blood sugar level were as follows; Normal A1C test being < 5.4% and Diabetes being >5.4%. Based on the Venous Blood Glucose tests method, 89.0% (154/173) respondents tested normal, while 11.0% (19/173) had diabetes. However, capillary blood glucose testing method identified 78.6% (136/173)5 respondents as being normal compared 21.4% (37/173) having diabetes. Results obtained from the process indicate capillary glucose blood test for gestation diabetes having very low sensitivity i.e. 30% for gestation diabetes.*

The findings of the study will help to create public awareness on disease burden, improved diagnosis, classification, management and health policies by the Ministry of Health about Gestational diabetes among Ugandan mothers.

Conclusion*: Most of the procedures employed to detect and trace for GDM was found to be painful and stressful. The healthcare providers and managers some lacked required skills and knowledge concerning GDM among women and procedural handling was found to be wanting in one case or another. The GDM prevalence was discovered to be slowly increasing even though it was detected*

to be at low levels at Nsambya hospital but the situation elsewhere might be different. Most of the GDM risk factors were majorly originating from family background, maternal ages discrepancies, and abuse of alcohol. Most GDM challenges were found to be fueled by lack of proper counseling and screening since it wasn't routine among health care professionals hence lack of expertise and inconsistencies in handling GDM women. Preparing women for GDM screening and diagnosis would have reduced the risks and health challenges faced by pregnant women if they are well prepared and trained before subjecting them to the GDM testing.

Keywords: Gestational Diabetes Mellitus (GDM), Glucose Testing Methods (GTM), Capillary Blood Glucose (CBG), Venus Plasma Glucose (VPG).

Introduction

Based on the World Health Report 2012, 60% of the challenges due to diabetes and other non-communicable diseases occur in developing countries. The disease is costly with profoundly hard implications which are life threatening among patients [1]. Recent research studies on GDM in Sub-Sahara Africa showed a prevalence of about 14% with challenged complications in the management of the disease and how to prevent the complication that accompany diabetes with time [2].

Medical examination detects illness or disease risk factors in individuals otherwise well to treat early on and minimize morbidity and death. WHO recommends testing of 2-hour 75 g OGTT and diagnostic plasma concentration greater than 140 mg/dl (7.8 mmol/L) for expectant mothers, impaired glucose tolerance test > 140 mg/dL and is < 200 mg/dL and fasting plasma glucose < 126 mg/dL. A fasting plasma glucose > 126 mg/dL and / or 2 hour post glucose > 200 mg/mL would indicate undetected diabetes prior to conception [3]. In spite the recommended GDM screening during prenatal care worldwide and local standards, it has been shown that the procedure is poorly implemented. A further difficulty is the lack of consensus on worldwide and local consistence on GDM screening and diagnosis guidelines.

Symptoms of marked hyperglycaemia that occurred in poorly managed GDM included frequency in urination, fatigue, size reduction, nausea, and impaired vision. Many life-threatening conditions due to uncontrolled hyperglycaemia occur in many people with diabetes. Other complications of diabetes included retinopathy with potential loss of vision; renal failure; nerve disorders, amputations, joint pains, cardiovascular, loss of sexual desire, high blood pressure and abnormalities in protein metabolism [4].

During prenatal care, diseases such as gestational diabetes mellitus (GDM) were critical for detection complicate pregnancy. Pregnant mothers diagnosed for diabetes (GDM) were at a high risk of turning to type 2 diabetes with metabolic orders in the future. Timely diagnosis and management, not forgetting preventive care could help overcome this risk. However, available research data was not enough to fully explain the increasing trends of GDM especially in the developing countries. The objective for the research was to evaluate blood glucose of capillary sample and venous plasma glucose assays in pregnant women, the sensitivity and specificity of capillary blood testing of all women during antenatal care.

Methods

The study was a hospital based cross-sectional and descriptive study that employed both quantitative and qualitative methods of data collection. In the study, we recruited pregnant mothers seeking care at St. Francis Hospital Nsambya. Eligible mothers were enrolled in to the study and a pre-tested pre-coded standardized structured questionnaire was administered. This questionnaire was used to look for risk factors per mother's socio-demographic characteristics. These mothers were screened for GDM using capillary and venous blood glucose methods and determine the utility of the two test methods [4].

This determined the level of awareness of glucose testing methods and the gestation age (Trimester) with the lowest level of capillary and venous blood glucose levels among pregnant Women at St. Francis Hospital Nsambya, Kampala, Uganda.

Study period

In this study a mixed descriptive Qualitative and Quantitative method of data collection among pregnant women attending antenatal care at St. Francis Hospital Nsambya. The study was carried out between July and August 2020 at St. Nsambya Hospital Nsambya, an urban, tertiary care facility located in Kampala, Uganda. The study setting took place in the Antenatal Clinic of the Obstriatics and Gynaecology Department. The study catered for pregnant women from Kampala, and surrounding districts who attended antenatal clinic from the study unit. In the month of July pregnant women were interviewed about Gestational Diabetes Mellitus. The GDM messages in pregnancy were given to all pregnant women and encourage them to test for better maternal foetal outcomes. Women who were identified with GDM were enrolled into care for GDM.

Study population

Selection criteria: The target population of this study comprised of all pregnant women attending care at St. Francis Hospital Nsambya estimated to be approximately 1000 and aged between (20 – 30 and 30-40) years, the key stakeholders engaged, and other key informants related directly and indirectly to Socio-economic determinants of screening, diagnosis, management, stakeholders engagement and pregnant women in Makindye division, Kampala, Uganda. Systematic random sampling procedure was used where pregnant mothers were chosen as they registered and after sharing with them about the study and upon consent was recruited into the study. The recruitment was done from mothers who attend Antenatal clinic from August to September consecutively. The principal investigator (PI) and two pre-trained research assistants were stationed at the antenatal Clinic at 8am Monday to Friday.

Data collection: During the registration process, information about the study was shared to the study participants and their written informed consent was sought. The questionnaire was administered to those who had consented and after that blood was drawn for the tests by the laboratory phlebotomist who took off a blood sample by making a single print and secured the site of pick with gauze/cotton and plaster to stop any bleeding. Both Capillary and venous blood samples in which plasma/serum was taken from a mother and glucose levels estimated using a One touch (Roche Diagnostics) code 298 and plasma calibrated glucometer and Roche Cobas C311fully automated Chemistry Analyzer respectively. Both whole blood glucose and plasma/serum glucose was determined as per the principle of enzyme hexokinase (HK) catalyzes the reaction between glucose and adenosine triphosphate (ATP) to form glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). In the presence of nicotinamide adenine dinucleotide (NAD), G-6-P is oxidized by the enzyme glucose-6-phosphate Dehydrogenase (G-6-PD) to 6-phosphogluconate and reduced nicotinamide adenine dinucleotide (NADH). The increase in NADH concentration was directly proportional to the glucose concentration and was measured spectrophotometrically at 340 nm.

Statistical analysis: The data was cleaned and analyzed using the SPSS package, the information obtained from the rapid capillary plasma glucose diagnostic test was compared with the gold (Venous plasma glucose test) standard summarized in a two-by-two table and McNemar's graph plotted to compare the sensitivity and specificity. McNemar's test was applied to determine the difference between capillary and venous blood glucose data with cut off points (standard) for the positive and negative values among the collected blood glucose samples from pregnant women. This was applied in a two by two table after categorizing data (positive/negative) to determine the true positives among the study group (pregnant women). The Receiver operator characteristic and Area under curve analyses was analyzed to determine the predictive power of the constructed equation of Sensitivity, specificity, false positive rate and false negative rate was computed to validate the capillary method against venous method in testing/detecting glucose among pregnant women. Correlation analysis to evaluate the strength of relationship between capillary and venous glucose levels (variables) was done. Qualitative data was presented in tables, graphs, and pie charts, proportions (percentages), ranges including inter quartile range while the Quantitative data, the glucose concentrations for both capillary and venous methods was captured in a two-by two table to plot McNemar's curve to compare the sensitivity and specificity between capillary and venous glucose methods.

Exclusion criteria:

All the pregnant mothers that didn't consent and visit the laboratory testing labs were excluded from this study.

ETHICAL CONSIDERATIONS: This study was carried out according to Mount Kenya University's ethical standards. The report for the research was presented to the Research Sub-Committee of Mount Kenya University. The Uganda Science and Technology Board and St. Francis Hospital Nsambya, research ethical review boards of whom after the authorization the study was carried out. Finally, the researcher sought the consent of participants who were informed of the research standards, written consent and signed after translating it into local language as well.

Results

Description of the studied population: The study revealed that more women aged between 25 and 30 years with 45.7% are more interested in getting involved in testing for GDM than those of less than 25 years with 20.2%, 31 to 34 with 21.4% and respondents 35 years and above with 12.7%.T the average body weight and height for the pregnant women was 87.5 kgs and 159.8 (7.2) cm, 37.4% of women had a BMI of 30 kg/m² , with those between 25-30 kg/m2 and below 25 kg/m2 being 33.5% and 19.1% respectively. That 73.4% of the women seeking ANC and getting involved in knowing their GDM are married and sometimes their husbands escort them while visiting ANC clinics. Fourteen percent of the women were cohabiting, 13% widowed, and 9% were single mothers. The survival rates of neonatal are higher among ANC attendants and any post pregnancy complications are reduced due to the uptake of ANC services including GDM which is the lead cause of preterm babies in Uganda.

The tests for both capillary and Venous Blood Glucose were based on the principle of glucose oxidase test. Cutoff for the different blood sugar level were as follows; Normal A1C test being < 5.4% and Diabetes being >5.4%. Based on the Venous Blood Glucose tests method, 89.0% (154/173) respondents tested normal, while 11.0% (19/173) had diabetes. However, capillary blood glucose testing method identified 78.6% (136/173)5 respondents as being normal compared 21.4% (37/173) having diabetes.

Table 1: To determine the sensitivity and specificity of capillary and venous blood glucose methods among pregnant women at St. Francis Hospital, Kampala, Uganda.

		Venous		
Capillary	Test	Negative	Positive	Total
	Negative	128	8	136
	Positive	26	11	37
	Total	154	19	173

Results indicated that capillary glucose blood test for gestation diabetes having very low sensitivity i.e. 30% for gestation diabetes.

Trimester with the lowest level of capillary and venous blood glucose levels among pregnant women. Data collected from 173 pregnant women revealed that in both Venous and Capillary glucose methods, the lowest level of blood glucose was observed in the 2nd trimester with 3.01 and 3.9 mmol for venous and capillary respectively.

Discussion

The uptake for GDM screening during pregnancy was observed to be 98.28%, giving a positivity rate of 1.72% among women who visited antenatal care clinic at St. Francis Hospital Nsambya during the period of study. The study's level of awareness of glucose testing methods among 173sampled pregnant women was 29.8 %, with sensitivity and specificity of capillary versus venous blood glucose was 30%, and 94% respectively. The trimester with the lowest level of capillary and venous blood glucose levels were 2nd trimester with 3.9mmol and 3.01mmol respectively. Study results indicate poor performance of Capillary blood glucose testing method for use in the antenatal care clinic considering the accuracy of 80% and the positive and negative LHRs of 1 and 0.7, respectively.

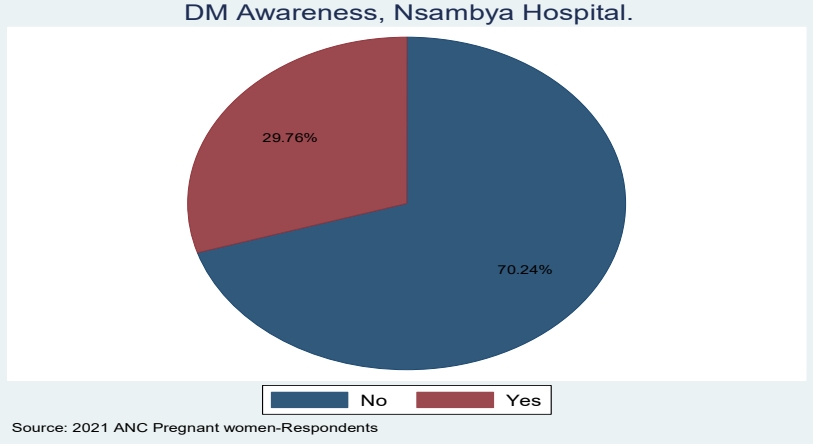

Figure 1: To determine the level of awareness of glucose testing methods among pregnant Women at St. Francis Hospital Nsambya, Kampala, Uganda.

Using capillary had very low with sensitivity, specificity, and accuracy of 30%, 94%, and 80% respectively for capillary versus venous blood glucose monitoring methods. During pregnancy, a woman's body requires more insulin because the placenta produces extra glucose. Along with hormonal changes, this can make it difficult for a woman's body to regulate glucose. When the body cannot produce enough insulin, a pregnant woman may develop gestational diabetes. Disorders that can cause hypoglycaemia include; pancreatic tumors, organ failure, hormone imbalances, particularly in cortisol and glucagon, deficiencies of certain enzymes, recent stomach surgery. Medication such salicylates or pain relievers, including aspirin, antibiotics, sulfa drugs, pentamidine, pneumonia medication, malaria mainly quinine, Lifestyle factors (not eating enough exercising more than usual, drinking alcohol, having an eating disorder), and morning sickness usually with vomiting frequency.

Variant to this study outcome, different sensitivity, specificity, and accuracy of 85.0%, 95.0%, and 90.3% respectively were obtained for the diagnosis using capillary sampling. Likewise, low results of 58%, and 83% compared to 83% and 96% for positive predictive value (PPV) and negative predictive value (NPV) [6]. Similar to results obtained by[6], albeit with differences between capillary and venous P-glucose in fasting [7]. Reported a sensitivity and specificity of 84% and 98%, respectively, using capillary sampling. These results differ from those observed in this study where we found a lower sensitivity and similar specificity of 30% and 94% respectively. The positive and negative LHRs of 5.1 and 0.7 indicate that capillary sampling is not a very reliable method since a positive LHR below 10 indicates a very low probability for correct diagnosis. However, this could be due to poor measurement, and preparation of sample due to poor training for midwives in phlebotomy methods. Table 2: Similar to other study findings, the capillary and venous blood glucose levels are lower in the 2nd trimester. In their study, Aruna and others found lower mean blood glucose level for capillary method to be 20.2% in the second trimester compared to 10.6% in the third trimester [8].

Table 2: Calculation for sensitivity and specificity using venous blood glucose test as the gold standard

Test performed	Formula	Results
Overall perfect correct		80%
Sensitivity	(True Positives)/(True Positives)+False Negatives)	30%
Specificity	(True Negatives)/(True Negatives)+False Positives)	94%
Positive Predictive Value (PPV)	(True Positives)/(True Positives)+False Positives	58%
Negative Predictive Value (NPV)	(True Negatives)/(True Negatives)+False Negatives)	83%
Positive Likelihood ratio LR+	Sensitivity/(1-Specificity)	5.1
Negative Likelihood ratio LR-	(1- Sensitivity)/Specificity	0.7

Limitations of the study:

In diagnosis: Various studies have shown there are a significant number of false positives. So, it is clear that CBG cannot be used for diagnosis of GDM but perhaps can be used as an initial screening test in resource-constrained settings. CBG values are found to be higher when compared to venous sample due to slow metabolism of glucose in peripheral tissues. Several factors influence the CBG measurements performed by different methods. Arterial blood shows higher glucose values than venous blood. The difference may be due to the balance between the water and glucose in the analysed blood, and also due to different glucose meters used, environmental exposure (e.g., moisture, altitude) can affect the accuracy of glucose meter results.

In data collection: adequate training for imparting skills and knowledge to the field staff to perform the CBG test correctly was quite challenging. Clinical errors may also alter the accuracy of glucose meters. Condition of anemia among pregnant mothers has been noted to alter the findings where such conditions are found to have a higher prevalence.

Conclusion:

In our study area of St. Francis Hospital Nsambya, Kampala we discovered a modest prevalence of GDM (21.4%). Although practical for the widespread GDM screening of expectant women in low resource settings, the VBG GDM screening methodologies we reviewed were shown to have a poor sensitivity in our study sample. The bulk of GDM positive individuals (11.0%) were found with GDM after Capillary Blood Glucose (CBG) testing as compared to the venous tests (21.4%) diabetic as examined. In our study area of St. Francis Hospital Nsambya, Kampala we discovered a modest prevalence of GDM (21.4%). Although practical for the widespread GDM screening of expectant women in low resource settings, the VBG GDM screening methodologies we reviewed were shown to have a poor sensitivity in our study sample. The bulk of GDM positive individuals (11.0%) were found with GDM after Capillary Blood Glucose (CBG) testing as compared to the venous tests (21.4%) diabetic as examined.

Effective GDM treatment can help avoid future diabetes in the mother and child in addition to unfavourable maternal and perinatal outcomes. It is crucial to do universal screening in Uganda, regardless of the method chosen. Future clinical practice should create simpler and more efficient methods to eliminate the requirement for an OGTT. Risk of unfavourable outcomes in the research was extremely low when fasting plasma glucose was 4.4 mmol/l (80 mg/dl). Before suggesting FPG as a screening technique that can possibly detect pregnancies with extremely low risk of GDM, further research must be done on that aspect. Findings after the process indicates that capillary blood glucose test for gestation diabetes shows a very low sensitivity i.e. 30% for gestation diabetes.

After reading through every connected article on GDM, one crucial point that stands out is how diverse and changeable the Ugandan population is, making it difficult to draw firm conclusions about it using international standards. Hence, more comparative research on various diagnostic criteria in light of pregnancy outcomes is required.

What is already know on this topic

Usually, ladies with hyperglycaemia identified during pregnancy are at more noteworthy chance for adverse outcomes in pregnancy while as it continues to increase these women globally.

The available data on hyperglycaemia is still limited and depends upon the location and the study population mainly within the sub-Sahara Africa.

In Uganda, POC isn't commonly utilized in the screening of Glucose levels in the routine medical outpatient clinics however; consolidation of glucose screening among women seeking antenatal services and who may be at risk of GDM can prevent poor outcomes of pregnancy.

What this study adds

The study will increase the level of awareness of gestational diabetes among pregnant women, how to prevent this disease in pregnancy and subsequent outcomes.

Consequently, antenatal mothers will acquire more knowledge on the accessibility of POC in the detection and self monitoring of hyperglycaemia in pregnancy.

Competing interests

In this study, the author declares no competing interest.

Authors' contributions

Martin Mugenyi as the principal investigator was involved in all stages of this study from conceptualization, proposal writing, methodology, data collection, and formal data analysis. My supervisors; Dr. Joseph Juma Nyamai and Dr. Esther Muitta were involved in the guidance and review of the study. The biostaticians Dr. Silver Bahendeka, Michael Lwetabbe, Yasson Twinomujuni, Dr. Christine Kihembo who deeply participated in organizing and analysis data, initiated the draft manuscript, reviewed and edited the manuscript for submission. All authors for their reviews, guidance and approval of this manuscript for submission and publication.

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