Journal of Health, Medicine and Nursing
ISSN 2422-8419 An International Peer-reviewed Journal
Vol.54, 2018

Comparative Study of Oral Glucose Tolerance Test Levels in Pregnant Women Using Glucometer and Laboratory Glucose Oxidase Methods

WANKASI, M.M.[1]*, AGORO, E.S[2]., ALABRAH, P.W[3].

1. The Department Of Medical Laboratory Science, College of Health Science, Niger Delta University, Wilberforce Island, Bayelsa State, Nigeria.
2. Enis Biomedicals (eBm) LTD, Igbogene Epie, Yenagoa, Bayelsa State, Nigeria.
3. The Department of Obstetrics and Gynaecology, Federal Medical Centre, Yenagoa, Bayelsa State.

* Corresponding Author: E-mail: mieebiwankasi@yahoo.com: Tel.: 08064041614

ABSTRACT

Oral glucose tolerance test (OGTT) is a medical test utilized mostly to resolve border results involving glucose concentrations. This study is aimed at establishing an existence of relationship of OGTT glucose concentrations between glucose oxidase and glucometer methods. Blood samples were collected from hundred (100) pregnant women with risk factors for gestational diabetes mellitus. The glucose concentrations were assayed using glucose oxidase and glucometer methods. The results were analyzed using student *t*-test and Pearson correlation. The results established a significant increase ($P< 0.05$) of some of components of OGTT in glucometer method as compared to glucose oxidase method. A correlational study established a correlationship at only the fasting levels of the assay. The findings revealed that results from glucometer seem to be higher when compared to glucose oxidase method. Hence, glucometer should be restricted to only medical screening and not clinical use. Also users of glucometers should be educated on the inaccuracies surrounding the use of glucometer.

INTRODUCTION

Pregnancy, also known as gravity, is the time during which one or more offspring develops inside a woman[1]. Pregnancy is affected adversely by gestational diabetes mellitus. Gestational diabetes increase the risk of pre-eclampsia, and requiring a caesarean section. Babies delivered by parturients with poorly treated gestational diabetes are at increased risk of macrosomia, postpartum hypoglycemia and jaundice. If untreated, it can also result in miscarriage and intrauterine death. In the long term, the children are at a higher risk of being overweight and developing type 2 diabetes mellitus[2]. For an effective diagnosis and treatment of gestational diabetes, oral glucose tolerance test (OGTT) is required.

Glucose concentration is the amount of glucose present in the blood of a human or animal. The body naturally, tightly regulates blood glucose levels as a part of metabolic homeostasis[3]. As a primary energy source in human, it is used as a biomarker for the detection of diabetes mellitus. Determination of glucose concentration in the body usually employ arrays of sample types such as; fasting blood sugar, random blood sugar, 2 hours postprandial or oral glucose tolerance test (OGTT). Oral glucose tolerance test is the core of this study.

Oral glucose tolerance test (OGTT) is a medical investigation in which oral glucose is given and blood samples are taken at timed intervals to determine how quickly it is cleared from the blood stream[4]. It is used to investigate for gestational diabetes, insulin resistance, impaired beta cell function, and sometimes reactive hypoglycemia and acromegaly, or rarer disorders of carbohydrate metabolism[4]. Oral glucose tolerance tests (OGTT) involved the administration of a standard dose of glucose (75g) with the subsequent checks of glucose blood levels for up to two and half hours[5].

The procedure is invasive and inconveniencing as venipuncture is done six (6) times, coupled with the laborious laboratory technique. Also, the turnover time is another disadvantage when utilizing laboratory technique, especially on an emergency. In an attempt to circumvent the handicaps of employing the oral glucose tolerance tests as stated above, the emergence of rapid test kit is gradually gaining foothold in the management diabetes mellitus.

The rapid test kit utilized for this study is the glucometer. A Glucometer (Glucose meter) is a medical device for determining the approximate concentration of glucose in the blood. It is a key element of home blood glucose monitoring (HBGM) by diabetics[6]. A small drop of blood, obtained by pricking the skin with a lancet, is placed on a disposable test strip that the meter reads and uses to calculate the blood glucose level. The meter then displays the level in units of mg/dl or mmol/L[6].

Due to the series of venipuncture (with the associated pains/inconvenience) and the time constrain observed using laboratory procedure; there arise the need for a more suitable technique that will help alleviate these observed pitfalls. Hence, the study aims to undertake a comparative evaluation of the reliability and accuracy of the glucometer and the glucose oxidase (spectrophotometer) method in determining glucose concentration, in oral glucose tolerance test in pregnant women.

MATERIALS AND METHOD

Area of Study

The research was carried out at the Federal Medical Centre Yenagoa, Bayelsa state, Nigeria. Bayelsa state is located within Latitude 4^0 15^1 North and Latitude 5^0 and 23^1 South [7]. It is also within longitude 5^0 22^1 West and 6^0 45^1 East. It is bounded by Delta State on the North, Rivers State on the East and the Atlantic Ocean on the Western and Southern parts. According to the 2006 census figures, Bayelsa has a population of about 1.7 million people[7].

Study Population

A total of one hundred (100) pregnant women who gave consent, were recruited for the study. The study group was selected from patients who presented for routine antenatal clinic visit. Such patients have identified risk factor(s) for GDM but no manifest symptoms of diabetes mellitus.

Sample Collection

The prerequisites as prescribed by the World Health Organization (annex 1)[5] were observed. A total of 4mls of venous blood was collected from the subjects into a sodium fluoride oxalate containers. The samples were centrifuged at 3,500rpm for 5minutes and the plasma separated for the laboratory analysis using the spectrophotometer. Whereas, for the glucometer, finger pricks were performed for all the subjects. For both groups a total of six (6) blood samples were collected (at zero hour and then half hourly for 2½ hours).

Estimation of Glucose

Plasma glucose was estimated spectrophotometrically using glucose oxidase method, whereas that of rapid test kit utilized glucometer. The standard operating procedure (SOP) of both methods as stipulated in the manual was strictly followed.

Ethical Clearance

The ethical clearance was approved by the ethics committee of the Federal Medical Centre, Yenagoa, Bayelsa state, Nigeria. Details of the study was carefully explained to each subject and an informed consent obtained from them before recruitment into the study

Statistical Analysis

The statistical analysis was done using the SPSS windows versions 21. Test of significance was determined using the student *t*-test and the statistical significance was set at $p<0.05$. Pearson correlational analysis was utilized to evaluate the relationship between the two methods.

RESULTS

Table I: Comparison of OGTT between Glucometer and Spectrophotometer Methods in Pregnant Women

OGTT TIMINIG (MINS)	Glucometer (Mean±SD)	Glucose Oxidase (Mean±SD)	P-value
FBG	5.5 ±1.0	3.6 ±0.8	P < 0.05
30 MINS	10.3 ± 3.0	9.7 ± 2.5	P>0.05
60 MINS	6.9±2.7	5.1±0.7	p<0.05
90 MINS	5.2±1.3	5.0±1.3	P>0.05
120 MINS	5.4±1.0	4.2±1.0	P<0.05
150 MINS	5.9 ±1.0	4.9±1.0	P<0.05

Legends

P < 0.05 – Significant P > 0.05- Non-Significant

S-Significance; NS-Non-significant difference;

FBG- Fasting Blood Glucose; OGTT-Oral Glucose Tolerance Test.

Table I showed a significant decrease (P < 0.05) in fasting blood glucose compared between glucometer and glucose oxidase methods. The Oral Glucose Tolerance Test result for 30 and 90 minutes did not exhibit significant difference (P < 0.05). However, 60, 120 and 150 minutes exhibited a significant increase (P <0.05) as compared above.

Table II: Observed Pearson's correlation between Glucometer and Spectrophotometer.

OGTT (MINS)	R	LEVEL OF SIGNIFICANCE	P-VALUE
FBG	0.756	0.004	P<0.05
30MINS	-0.124	0.701	P>0.05
60MINS	-0.452	0.140	P>0.05
90MINS	-0.092	0.775	P>0.05
120MINS	-0.278	0.382	P>0.05
150MINS	-0.278	0.382	P>0.05

Legends
P < 0.05 – Significant
P > 0.05- Non-Significant
FBG=Fasting Blood Glucose;
r = Pearson's correlation;
S=Significant difference;
NS=Non Significant difference.
Table II showed that only FBG exhibited significant correlation between glucometer and glucose oxidase methods, other components of OGTT did not correlate.

DISCUSSION

Gestational diabetes mellitus is pregnancy induced and is associated with an increase in perinatal and maternal morbidity and mortality. This underlines the importance of early detection and proper management especially when the risk factors for gestational diabetes mellitus exist.
Physicians utilized a regimented medical laboratory analysis for its management. One of the regimes is oral glucose tolerance test (OGTT). Oral glucose tolerant test aids the diagnosis and treatment of gestational diabetes. Borderline results emanating from glucose test is usually resolved with OGTT. The research was conducted to critically analyze the possibility of replacing glucose oxidase with glucometer as method of choice.

The study revealed that glucose concentrations of glucometer were higher than those with the glucose oxidase method (spectrophotometer) but this was statistically significantly ($P < 0.05$) at 0, 30, 120 and 150 minute respectively (Table I). Furthermore, a correlational study only showed a significant correlation between fasting blood glucose concentrations between glucometer and glucose oxidase. Other components of OGTT; 30, 60, 90, 120 and 150 minutes glucose exhibited no correlations (Table II).

The findings explicitly show that glucometer results when compared to spectrophotometer overestimated glucose concentration and this agrees with the report by other authors.[8-11] Similarly, these authors[8-11] have also raised the question about the reliability of glucometers especially at extreme of values. At these critical hyperglycemic values glucometers show the maximum discrepancies and least correlation with centralized laboratory [12].

The reasons for the overestimation of glucose concentrations observed in glucometer are myriad. Glucometer and its strips ought to be stored at optimal temperature; deviation from such affect glucose results adversely. Glucometer utilize enzymes which are susceptible to temperature fluctuations[13]. Enzymes are known to be vulnerable to undesirable temperature.

Other reasons include operational factors and faulty blood application[14-16]; the most common reasons are applying insufficient blood sample to the strip, expired strips, strips exposed to excess moisture or humidity, improper code, dirty meters, improper cleaning of the testing site and hemolysed sample.

Due to the complications of gestational diabetes mellitus and the question of result reliability, medical professionals should ensure glucose oxidase method is utilized for OGTT. It is also the view of the authors that, medical laboratory scientists, clinicians and other end users should evaluate the performance of glucometer periodically[16].

In resource limited settings the use of the glucometer can be handy due to its low cost. Therefore, this study does not support the increasing opinions for the discontinuous use of glucometers, but their use should be restricted to medical screening and not in the management of diabetes mellitus and other medical complications.

Conclusions

The use of glucometer for blood glucose testing is very simple, rapid and cost effective. On the contrary, glucose oxidase method despite its longer operational time and higher cost burden is still a more reliable method for the diagnosis and management of the patient. The finding in our study suggests that glucometer tend to overestimate the concentration of blood glucose. Hence border results analysis that require high level of accuracy and precision should not be determined using glucometer, rather the glucose oxidase method should be the method of choice.

References

1. Wylie, CE. Fertilization, the embryo and the foetus. In: Wylie CE editor. Essential Anatomy and physiology in maternity care 2nd ed. Edinburgh: Churchill living stone 2005. P172
2. Chu SY, Callaghan WM, Kim SY, Schmid CH, Lau J, England LJ, et al. Maternal obesity and Risk of Gestational Diabetes Mellitus. Diabetes care.2007:30(80):2070-76.
3. Burtis, C.A., Ashwood, E.R., and Browns, D.E. (2008). Glucose Biochemistry and physiology: Carbohydrate, part iv Analysts. Tietz fundamentals of Clinical Chemistry (8TH Ed.) Saunder'sElseriel, Delhi page 376-7.
4. Defronzo RA, Abdul-Ghani M. Assessment and treatment of cardiovascular risk in prediabetes. Impaired glucose tolerance and impaired fasting glucose. Am J of Cardiol 2011:108 (3):3B-24B.
5. World Health organization and international diabetes federation (1999). Definition, diagnosis and classification of diabetes mellitus and its complications. Geneva, Switzerland: World health organization.
6. Alkire RC, Kolb DM, Lipkowski JB. (2011). Bioelectrochemistry: Fundamentals, Applications and Recent Developments. Weinheim: Wiley – VCH.
7. Agoro, ES, Ebiere NE, Eseimokumo SA, Odegbemi, JO. Is Saliva an alternative non-invasive sample for the estimation of protein profile amongst diabetics and gender-based diagnostics? Anatomy and Physiology: Current Research,2017:7:(2)255.

8. Reeves ML, Forhan SE, Skyler JS, Peterson CM. Comparison of Methods for Blood Glucose Monitoring. Diabetes Care 1981:30:404-6.
9. Khan AI, Vasquez Y, Gray J, Wians F, Kroll M. The variability of results between point-of-care testing glucose meters and the central laboratory analyzer. Arch Pathol Lab Med. 2006:130(10):1527-32.
10. . Baig A, Siddiqui I, Jabbar A, Azam SI, Sabir S, Alam S, et al. Comparison between bed side testing of blood glucose by glucometer vs. centralized testing in a tertiary care hospital. J Ayub Med Coll Abbottabad. 2007;19(1):25-9.
11. Clarke WL, Cox D, Gonder-Frederick LA. Evaluating clinical accuracy of systems for self-monitoring of blood glucose. Diabetes Care, 1987:10:622–8.
12. Chen E, Nichols J, Duh S, Hortin G. Performance evaluation of blood glucose monitoring devices. Diabetes Technol Ther, 2003:5:749–768.
13. Sharma SP, Anjanker AP, Kale A. Comparison of glucose levels using glucometer and GOD-POD MethoD. Int J Clin Biochem and Research, 4(1):6-10.
14. Bergenstal MD, Richard M. Evaluating the accuracy of modern glucose meters. Insulin. 2008;3(1):5–14. https://doi.org/10.1016/S1557-0843(08)80004-8
15. Johnson RN, Baker JR. Error detection and measurement in glucose monitors. Clini Chim Acta. Int J Clin Chem. 2001:307(1-2):61–7.
16. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet, 1986:1:307-10.