SHOULD WE ASSUME ACCURACY OF POINT OF CARE GLUCOSE METERS? AN OBSERVATION FROM A TERTIARY HEALTH CARE CENTRE.

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ABSTRACT

BACKGROUND: Self-monitoring of blood glucose is important in the management of patients with diabetes mellitus in the community as well as in the hospital. It has been used for calculation of insulin doses of individuals with dysglycaemia and monitoring of glucose control. Errors in the measurement of the blood glucose can lead poor management of a patient. There is therefore the need to ensure standardization of these meters in order to achieve accuracy and precision.

OBJECTIVES: To evaluate the precision and accuracy of four glucose meters commonly used for self-monitoring of blood glucose (SMBG) in a tertiary health care Centre compared to the reference laboratory method.

MATERIALS AND METHOD: We analyzed blood glucose samples of 55 diabetic patients who came to diabetes clinic using 4 different glucose meters (Accucheck active, Novo max extra, One touch Ultra 2 and On call plus (accoson)). Capillary and Venous blood samples were taken simultaneously from each patient for analysis using four blood glucose meters and laboratory reference method respectively. The laboratory value was used as a tool for comparison. The accuracy and precision were evaluated by the ISO and ADA criteria. The results obtained were analysed using Bland Altman graphs, correlation coefficients, scatter plots and Clarke's error grid analysis.

RESULTS: We observed good correlation between two glucose meters (Accucheck[TM] and Novomax[TM]) and laboratory analyzed values. Among the glucose meters Accucheck[TM], Novomax[TM], One touch Ultra[TM] and On call plus[TM], the correlation coefficient was 0.97, 0.96, 0.88 and 0.69 respectively. The degree of agreement of the laboratory method and the Accucheck[TM], Novomax[TM], One touch ultra[TM] and On call plus[TM] glucose meters was 89.09, 80.00, 76.20 and 71.32% respectively. Accucheck[TM] and Novomax[TM] were within ±20% accuracy (14.5% and 16.1%).

CONCLUSION: There is a need for adequate and appropriate evaluation of all glucose meters in our setting before that we deploy them for use. None of glucose meters met the ISO target. Only one glucose meter (Accucheck[TM]) met the ADA guideline for accuracy.

KEYWORDS: Accuracy; glucose meters; diabetes mellitus; self-monitoring of blood glucose.

INTRODUCTION

The prevalence of diabetes mellitus is increasing globally. In Nigeria, the prevalence has risen from 0.5% reported in the 1960s by Johnson et al.[1] in 1960s to 2.2% reported in by Akinkugbe et al[1] in 1990s. Recent meta-analysis by Uloko et al[3] showed a prevalence of 5.8%, this alarming trend in the increase calls for serious concern.

Self-monitoring of blood glucose is important in the management of patients with diabetes mellitus in the community as well as in the hospital. Studies have shown that there is a consistent relationship between glycaemic control and SMBG. A study in Lagos has reported a 3 decrease HbA1c levels of subjects who had SMBG compared to those who didn't.[4]

Additionally, SMGB has been utilized to adjust and calculate insulin doses at home by patients with diabetes mellitus and it has also been used for monitoring of blood glucose control. Therefore, errors in the measurement of the blood glucose can lead to dysglycaemia (hypo or hyperglycaemia) and wrong dosages administration. This goes to buttress the fact that there is the urgent need to ensure that blood glucose meters are accurate and precise.[4,5]

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It is however pertinent to note that blood glucose meters should not be used to diagnose diabetes mellitus in whatever circumstances. In utilizing blood glucose meters for measurements, the ISO recommends a total analytic error of 20%, while the ADA recommends an error of margin of 5%.

In practical times when using the ISO recommendation, a measured blood glucose of 5mmol/l will translate to an allowable margin of error of about 4 to 6mmol/l and 4.75 to 5.25mmol/l when using the ADA.[6,7]

The performance and suitability of blood glucose meters have been evaluated in many places but to the best of our knowledge, this is the first of such study in our environment.

The objective of this study was to evaluate the precision and accuracy of four blood glucose meters that are commonly used by patients for SMBG in our setting compared to the reference method.

MATERIALS AND METHOD

The study was conducted using four different glucose meters (Accucheck active™, Novo max extra™, One touch Ultra 2™ and On call plus™ (accoson)) that are commonly used by the patients who visit our diabetes clinic. Blood glucose samples of 55 diabetic patients who came to diabetes clinic were collected from the forearm veins. The four glucose meters were used to check the blood glucose of all the samples and a laboratory measurement was also done. The laboratory value was used as a reference for comparison.

First of all, the four blood glucose meters were used to measure the blood glucose of each of the 55 patients by applying a drop of blood from a single finger prick site to the meters. In doing so, the meters were utilized and rotated in order to avoid any meter from occupying a particular position during the test procedure. Additionally, the accuracy was evaluated by the ISO and ADA criteria. The results were evaluated by Bland Altman graphs, correlation coefficients, scatter plots and Clarke's error grid analysis.

Figure 1: Bland Altman graphs showing the Distribution of blood glucose values of various glucometers vs laboratory assayed values
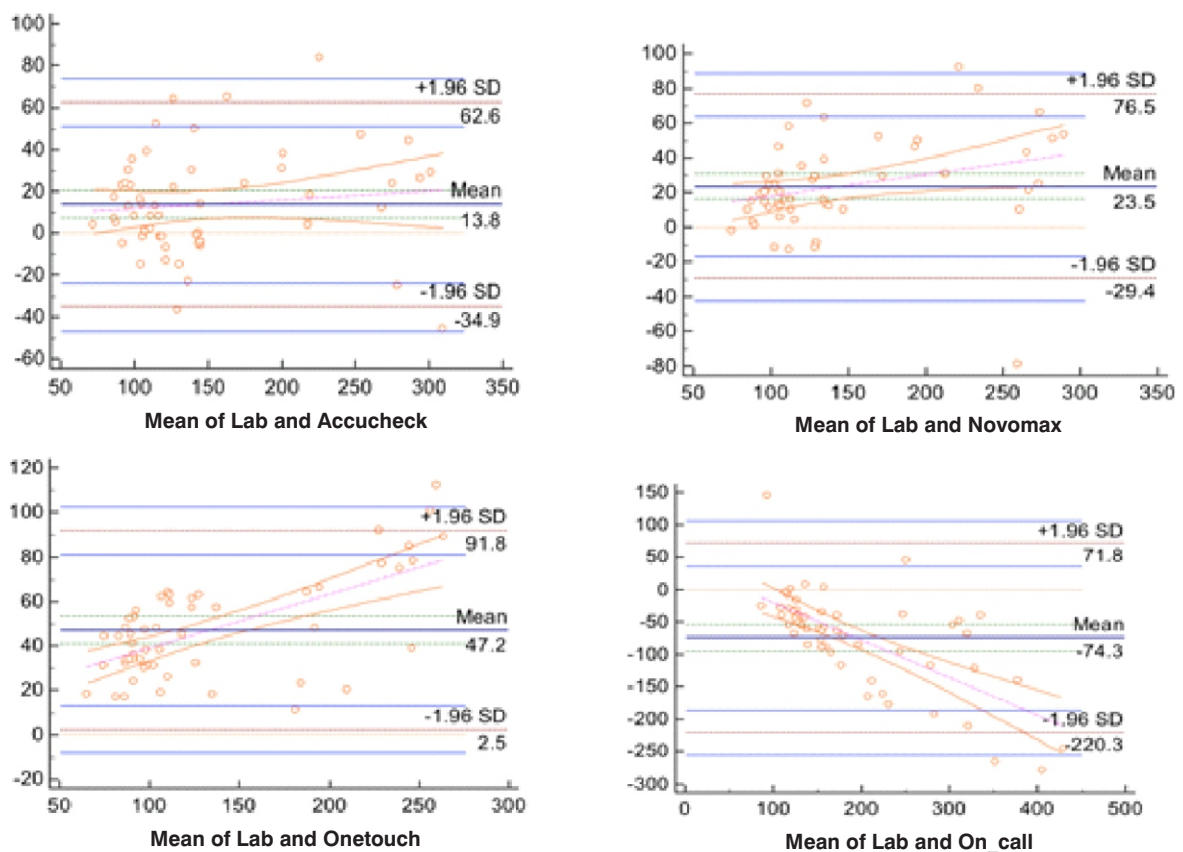
Figure 2: Park grid error analysis plot showing the distribution of blood glucose values of various glucometers vs laboratory assayed values
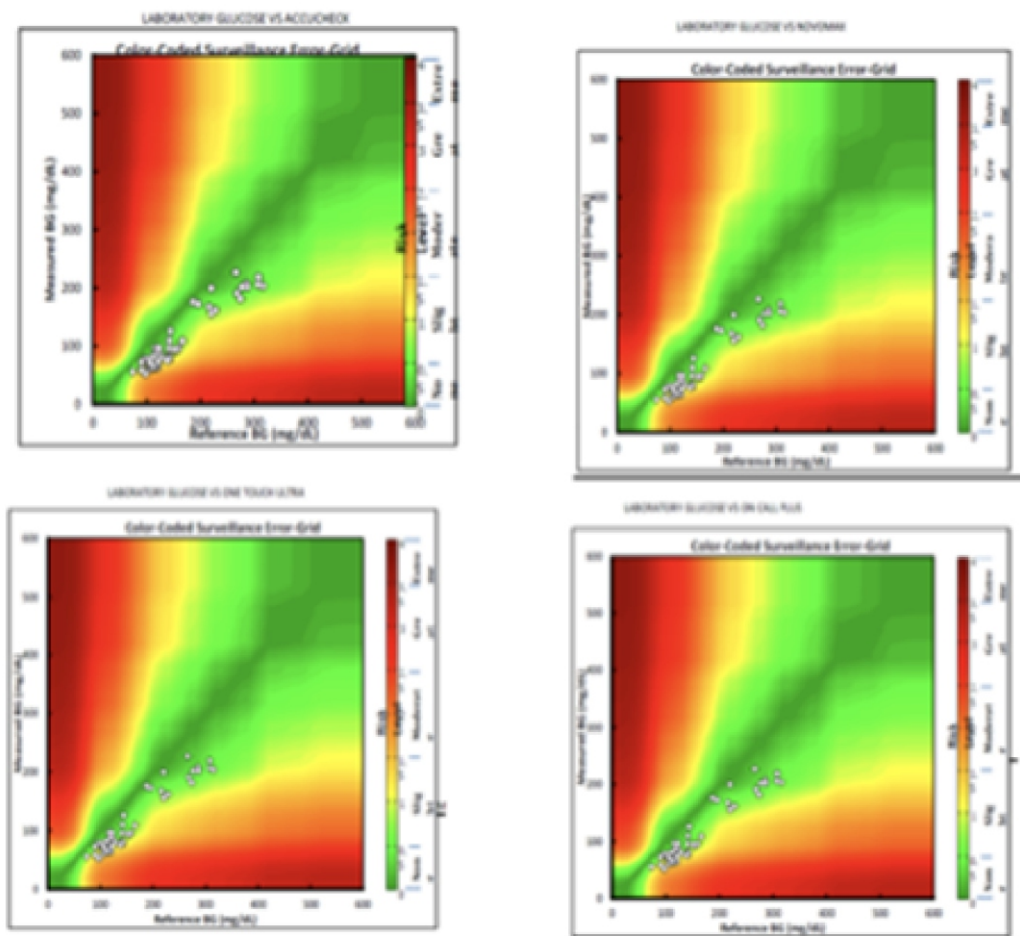
RESULTS

We observed good correlation between two glucose meters (Accucheck™ and Novomax™) and laboratory analyzed values. Among the glucose meters Accucheck™, Novomax™, one Touch ultra™ and On call plus™, the correlation coefficient was 0.97, 0.96, 0.88 and 0.69 respectively. The degree of agreement of the laboratory method and the Accucheck™, Novomax™, One touch ultra™ and On call plus™ glucose meters was 89.09, 80.00, 76.20 and 71.32% respectively. Accucheck™ and Novomax™ were within ±20% accuracy (14.5% and 16.1%).

Table 1: Showing the correlation between various blood glucose meters and laboratory reference values

	Accucheck Active	Novomax	One Touch Ultra	On call Plus
Correlation Coefficient	0.97	0.96	0.88	0.69
Degree of agreement with Laboratory Method	89.09 %	80.00 %	76.20 %	71.32 %

DISCUSSION

Glucometers have been used successfully in Nigeria for self-monitoring of blood early 80's. This is because of its handy nature and the ease to use by both skill and non-skill personnel with limited levels of modern education. Its portability makes it easy to carry about and has also given rise to its abuse by health workers.[11,12]

In our hospitals, various glucometers are found in various wards and clinics with no forms of calibrations and standardization. This has accounted for different results being generated for the same patient within the same facility with lots of errors undetected. Its presence in all clinics and wards by different personnel has made quality control measures also non-existing.[11]

Accuracy and Precision of different glucometers is said to have improved over the past two to three decades. However, concerns have been raised about them meeting the ISO/NCCLS and ADA recommendations of less than 5% deviation when compared to a laboratory reference method. Studies have shown that there are variations in the accuracy of blood glucose meters.[12,13,14]

In our study, a group of four commonly used glucometers were subjected to analytical and performance scrutiny. Plasma and whole blood calibrations were performed with the various devices showing less than 5% Precision. A lot of discordance has been observed when these glucometers were compared with a reference laboratory range.

In our study, two (50%) of the assessed glucometers satisfy the ISO guidelines (i.e Norvomax™ and Accuchek active™) of ± 20% allowable analytical values when compared to a reference laboratory range. This result similar to the study by Essack et al, that was carried out in a tertiary centre like ours in South Africa where only 60% of the glucometers met up the ISO guidelines. This result is also not different from what was obtained from other developing countries of the world.[7]

The observed variability can impact negatively on patient care in settings like Intensive care units, Neonatal intensive care unit, Emergency Paediatric units, Labour wards, Accidents and Emergency units and Clinics.

CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

There is a need for adequate and appropriate evaluation of all glucose meters in our setting before that we deploy them for use. None of glucose meters met the ISO target. Only one glucose meter (Accucheck active) met the ADA guideline for accuracy.

Our study was limited by the fact that glucose oxidase method was used instead of hexokinase which is the reference method. Secondly the sample size was small (55 subjects).

We therefore recommend that glucose meter should be routinely calibrated in order to achieve standardization.

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