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RESEARCH ARTICLE

COMPARISON OF BLOOD GLUCOSE MEASUREMENT USING ILAB 300 PLUS AND POINT OF CARE GLUCOMETER IN MOSHUPA, BOTSWANA

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ABSTRACT

Background: Diabetes mellitus is a group of metabolic diseases characterized by elevated blood glucose concentration (hyperglycemia) resulting from either defect in insulin secretion by the pancreas, insulin action, or both. According to World Health Organisation, over 422 million people have diabetes in the world while 24 million people in Africa have the disease but this prevalence is expected to rise by 129% by 2045. **Materials and Methods:** Forty (40) samples were selected for testing and analysis. The glucose level of each patient was assayed using both the glucometer and glucose oxidase method with the samples run in duplicates and measured simultaneously.The results were compared using means, standard deviation, median (range), and correlation. **Results:** The means were 4.7 mmol/l for the reference method and 4.65 mmol/l for the On Call Plus. The results of the study were found to be comparable with a correlation coefficient of 0.9553 and an accuracy of 99%. The bias was 0.2350 and p-value < 0.0001. **Conclusion:**The study found a strong correlation coefficient of 0.9553 between glucose measurements with On Call Plus and the laboratory reference method, an accuracy of 99% between the two modes of testing, and an acceptable precision of less than 10% observed. The results are statistically significant with a p value of <0.0001. It is concluded that a comparability of results of On Call Plus glucometer to those of the ILab 300 plus could be obtained if the sources of error are minimized.

INTRODUCTION

Background and Literature

Diabetes mellitus is a group of metabolic diseases characterized by elevated blood glucose concentration (hyperglycemia) resulting from either defect in insulin secretion by the pancreas, insulin action, or both (Kanwugu et al., 2017). According to World Health Organisation, over 422 million people have diabetes in the world while 24 million people in Africa have the disease but this prevalence is expected to rise by 129% by 2045 (WHO, 2019). Currently, in Botswana, the prevalence rate of diabetes stands at 5.2% taking the sixth spot among the top ten causes of death in the country (Shiriyedeve et al., 2019).Testing and monitoring of this blood glucose are either performed using laboratory testing or point-of-care testing using glucometers. The use of glucometers is prevalent in clinical practice and has beneficial effects therefore there is need to ensure the reliability, accuracy and correlation of results at all the times. Comparability of Point of Care Testing results with laboratory testing results is therefore of paramount importance.

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Factors affecting the accuracy of results

A study carried out where 1837 glucose meters readouts from hospitalized patients were analyzed, established that inaccuracies in measurements may be related to the operator, including incorrect specimen collection, insufficient or incorrect application of blood to the strip, inappropriate sampling site, application of the specimen to the strip more than once, incorrect insertion of the strip into the meter, inaccurate timing, poor meter maintenance or cleaning, and poor storage of consumables of the device (Baygutalp et al., 2018). It has been established that several factors can affect glucometer readings which include pre-analytical, analytical, and post-analytical factors that could affect the accuracy of point-of-care glucometers (Ogunbosi et al., 2022).The authors further stated that pre- analytical factors included operator or strip related factors like particles on the test finger, wet or too dry fingers, wrong sample site selection, and expired or

strip exposed to humidity. Analytical factors include the test performance of the glucometer, environmental factors like temperature, humidity, and altered patient physiologic states. Temperature changes, especially hypothermia, increase the glucometer blood glucose reading on glucometers, while humidity cause a reduction in reading. It was mentioned that laboratory glucose testing is done on plasma (thus without the influence of hematocrit) and under more controlled conditions. This means that laboratory results are more accurate than glucometer readings. The authors' shared common sentiments when it comes to highlighting the factors causing inaccuracies in glucose testing.

Most literature relating to the current topic was mainly about validation of the glucometers used in patient management, using either critically ill patients as subjects or neonates or already diagnosed diabetic patients but little has been documented about other subjects like those without diabetes (random patients), or those without any metabolic disorders. Few studies in Botswana have been documented but not addressing the subject at hand. In this study, samples from the general population were tested and comparison of glucose concentrations measured using an On-Call Plus glucometer found at Mmaseetsele Laboratory in Moshupa, Botswana and medical laboratory testing using ILab 300 plus were analyzed.

METHODS

The observational cross-sectional study was performed at Mmaseetsele Clinic laboratory, in Moshupa, Botswana between the months of September 2023 to December 2023. Both random and fasting blood glucose levels were measured using both the point of care On Call Plus and ILab 300 plus simultaneously. Forty (40) residual samples were randomly received from within Moshupa Clinics and other facilities surrounding Moshupa Village and analyzed or tested using the rapid On Call Plus glucometer and the Glucose Oxidase method. Venous blood collected in sodium fluoride tubes was used for analyses on both modes of testing. Residual samples with a volume of atleast 3ml were included in the study while those with less than 1ml were excluded from the study.

Two (2) levels of Quality control samples namely SeraChem Control levels 1, 2 and were analyzed before sample processing to help validate the analyzers as well as to check the integrity of the reagents. The controls were plotted in a Levey Jennings (LJ) chart for acceptability and validation. As for the glucometer known levels of glucose samples were analysed and recorded as well.

Laboratory investigations

Samples were collected in a Sodium Fluoride tube with about 3ml of venous blood collected. Whole blood samples were collected as random blood glucose and transported in a cooler box with ice packs and stored at 2-8^{0}C before analysis. These samples were analysed first with On Call plus as its analysis was carried out using whole blood, the samples were then centrifuged for ten (10) minutes before analyses on the ILab 300 plus. Testing was based on the following principles;

Point of Care Testing

The On Call Plus Blood Glucose Test Strips are thin strips with a chemical reagent that works with the On Call Plus Blood Glucose Meter to measure the glucose concentration in whole blood. After the strip is inserted into the meter, a drop of whole blood approximately 0.5ul was applied to the sample tip of the test strip, and then automatically absorbed into the reaction cell where the reaction took place. A transient electrical current formed during the blood glucose concentration was calculated based on the electrical current detected by the meter, and then the result was shown on the meter display. The meter is calibrated to display plasma equivalent results.

ILab 300 Plus- Glucose Oxidase

Glucose oxidase catalyzes the oxidation of β-D-glucose to D-gluconic δ-lactone with the concurrent release of hydrogen peroxide. In the presence of peroxidase (POD), this hydrogen peroxide (H2O2) enters into a second reaction involving p-hydroxybenzoic acid and 4-amino antipyrine with the quantitative formation of a quinoneimine dye complex which was measured at 510 nm. The specimen of choice is plasma separated from a Sodium Fluoride tube.

Study Factors

Precision

Precision (within run / Repeatability)

Repeatability was demonstrated using two levels of controls on both ILab 300 plus and On-call Plus (3 different concentrations which are prepared in-house) on the same day for twenty (20) times. Mean, SD, and %CV was calculated and recorded for both modes of testing.

Accuracy

A minimum of five samples of different concentrations was analysed daily using both the On Call Plus glucometer and ILab 300 plus (analyses was done in duplicates to reduce sources of error) until 40 data points were reached, glucose measurements was then recorded. The accuracy was demonstrated by the use of the Bland Altman Chart determining the agreement between the two different assays and bias. The analysis estimated the differences between measurements and the mean difference, standard deviation, and 95% CI.

Correlation

The correlation was determined using linearity assessing the correlation between ILab 300 plus results and On-call Plus results. Samples' mean results were used for plotting the graph. The mean of two measurements per sample was used in plotting the data.

Statistical analysis

The data were captured into an excel spreadsheet and was analysed using Graph Pad Prism 6 software. A paired sample t-test was used to compare means between the laboratory reference method and the Glucometer. The Bland-Altman analysis was used to measure the extent of agreement or differences between the two modes of testing by determining accuracy and bias. The linear regression and Pearson correlation coefficient (r) was used to check for the association between ILab 300 plus results and On-call Plus results.

RESULTS

A total of 40 samples randomly selected were measured using

both methods of testing. Plasma concentrations for both modes of testing (reference method and glucometer) were found to be normally distributed and ranged from 2.6mmol/L-9.2mmol/L for reference method and 2.3mmol/L- 9.7mmol/L for glucometer testing as per Table 1. The measurements of the testing methods were grouped according to glycemic status of the samples mean, median and range calculated as per Table 1. 36 samples out of 40 samples were grouped to be of normoglycemic state for both testing methods. The mean and median for all groups were the same or with a slight difference.

The mean for both data setsanalyzed using reference method was 4.7mmol/L while data sets for the glucometer gave a mean value of 4.465mmol/L. The t-critical one-tail value of 1.685 and t-critical two-tail value of 2.022 were obtained whilst the p value was < 0.0001 using a paired sample t-test.

and that measured with the glucometer. 99% of the values were plotted within the 95% Confidence Interval (-0.4404 mmol/L-0.9104 mmol/L) with a bias of 0.2350 (Figure 1). Results indicated a strong agreement between the two methods. Accuracy was observed to be 99% as shown by the Clarke Error grid analysis chart (Figure 2).

Table 3 Comparison of mean, SD, and %CV values obtained from the Reference method and the Glucometer precision results

	Reference Method		On Call Plus Glucometer		
	Normal	abnormal	Level 1	Level 2	Level 3
Mean	4.245	15.145	2.615	5.215	19.205
SD	0.068633	0.060481	0.048936	0.153125	0.308605
%CV	1.616803	0.399343	1.871359	2.936248	1.606898

Table 1 Comparison of mean, median, and range of values obtained from the Reference method and the Glucometer results

	Reference Method (ILab 300 plus)			OnCall Plus Glucometer		
	Hypoglycemic (<3mmol/L)	Normoglycemic (3mmol/L-6mmol/L)	Hyperglycemic (>6mmol/L)	Hypoglycemic (<3mmol/L)	Normoglycemic (3mmol/L-6mmol/L)	Hyperglycemic (>6mmol/L)
No of samples	1	36	3	2	36	2
Mean	2.6	4.54	7.3	2.6	4.37	8.05
Median	2.6	4.45	6.5	2.6	4.4	8.05
Range	0	2.7 (3.3, 6)	3(6.2, 9.2)	0.6(2.3, 2.9)	2.4(3.3, 5.7)	3.3(6.4, 9.7)

Table 2 Comparison between the values obtained from the Reference method and the Glucometer results

Paired Two Sample for Means		
	Reference method	On Call Plus
Mean	4.7	4.465
Variance	1.249744	1.357718
Observations	40	40
Pearson Correlation	0.955279	
Hypothesized Mean Difference	0	
df	39	
t Stat	4.313132	
P(T<=t) one-tail	5.312105	
t Critical one-tail	1.684875	
P(T<=t) two-tail	0.000106	
t Critical two-tail	2.022691	

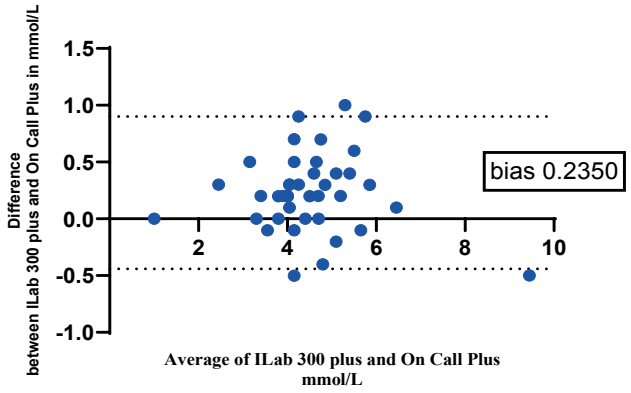

Figure 1 Bland-Altman plot of agreement between ILab 300 plus and On Call plus methods

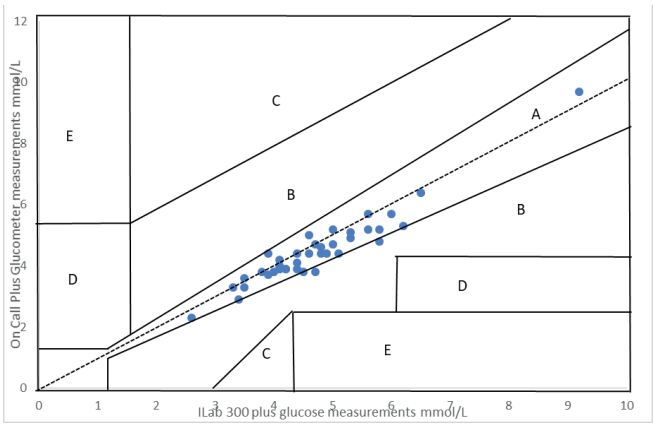

Figure 2 Clarke grid analysis between ILab 300 plus and On call plus methods

Precision results

Table 3shows the mean, standard deviations and %CV of the values obtained under precision. The %CV shows the precision or how repeatable the assay is. The observed %CV for both methods was less than 10% precision acceptable values.

The Bland Altman plot demonstrated good agreement between the levels of blood glucose measured by the reference method

Correlation analysis

The results showed a strong correlation between glucose levels generated by the reference method and the glucometer as indicated by the correlation coefficient (r) of 0.9553 (Figure 3), and a p value (two-tailed) of <0.0001 indicating that the results are statistically significant. However the r squared was observed to be 0.9126.

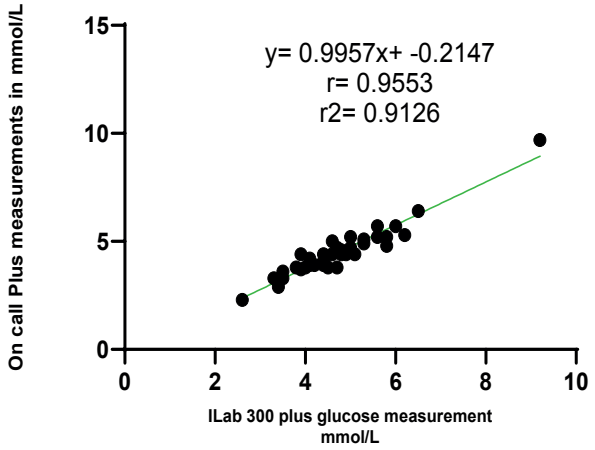

Figure 3 Correlation between the values obtained from the same sample by ILab 300 plus method and the On Call plus method

DISCUSSION

This study compared the glucose values obtained from On Call Plus with that obtained from the ILab 300 plus analyzer. Variation observed in the measurement of glucose is not unusual. In a laboratory set up where a lot of factors are involved in the pre analytical and analytical phases of testing this kind of observation may occur. Factors such as time of collection, type of anticoagulant used, transportation conditions, temperature and human errors may contribute to the outcome (Otokunefor & Ogu, 2018).

The accuracy was observed to be 99% as per the Clarke error grid analysis and the Bland Altman graph which means that the On Call Plus used in this study can be accurate in diagnosing patients' physiologic(glucose) status as the reference method and therefore can be used as a reliable source of testing for the management of Diabetes but clinicians need to take into consideration other factorswhich might affect the results. Factors such as exposure of test strips to sunlight and humidity, poor performance of the glucometer (controls not analyzed to validate the machine) and lack of competency of staff in using the glucometer.

The results of this study also suggest a strong correlation, excellent accuracy, and satisfactory agreement of blood glucose levels. A strong correlation of 0.9553 was observed between glucose levels generated by the glucometer and the reference method indicating a much stronger agreement between the two modes of testing. Thus, the On Call Plus glucometer used in this study is relatively accurate in measuring the glucose level of the patients and irrespective of their diabetes or physiological status. There was no notable influence of type of Diabetes mellitus on the glucose readings recorded by both methods.

A good correlation or concordance for the measurement at glucose concentrations of a maximum of 9.7mmol/L and minimum of 2.3 mmol/L is supported when simple linear regression wasapplied and yielded a slope of about 0.9957 and near-zero intercept of -0.2147, therefore regression associated with glucose concentrations between 2.3mmol/L- 9.7 mmol/L showed good concordance between On call Plus Glucometer and the laboratory's glucose oxidase method.

It can however be noted that although the precision of On Call Plus is known to fall within the 10% precision acceptable values, the equipment can be said to be not clinically specific as it could label some samples with normoglycemic status as hypoglycemic and it was also less sensitive because it was unable to pick correctly all those hyperglycemic sample values.

The current study confirms the findings of previous studies in which the arterial glucometer showed a strong correlation with the venous blood glucose, determined by a strong correlation (r = 0.973), and 100% accuracy (Bhurayanontachai, 2016). These findings of this study correspond to those from previous studies who found similar levels of correlation between the glucometer and auto analyzer (Mahoney & Ellison, 2007; Solnica & Naskalski, 2007).

Contributions

Jabane conceived the study. Both Jabane and Phuthego contributed in data analysisand provided input on interpretation of results and both authors contributed in writing the manuscript.

Declaration of interests

The authors declare no conflict of interest.

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