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ORIGINAL ARTICLE

Comparative Performance of Different Glucometers for Random Glucose Measurements in Diabetic Patients at Emergency Medicine Department of the Muhimbili National Hospital, Dar es Salaam, Tanzania

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ABSTRACT

Background: Proper management of diabetic patients is dependent on accurate patients' self-monitoring of blood glucose levels at home and during healthcare visits. Several glucometers are currently available in the market with variability in technical and clinical accuracy. The study aimed at assessing the performance of various glucometers and their reliability as tools worth depending on for patient blood sugar management.

Methods: This cross-sectional study involved 125 diabetic patients aged 39-59 years old comprised of 56 (47%) males and 69 (55.2%) females recruited from November 2022 to January 2023 at Muhimbili National Hospital Emergency Medicine Department. Patients' demographic and other relevant information were recorded using a questionnaire along with glucometer readings and the laboratory values of glucose. Bland Altman graphs, ISO 15197:2013, Consensus Grid Reference, were used to assess the technical and clinical accuracies.

Results: A total of 78 (62.4%) of participants did not have glucometers at home. The results showed five glucometers, namely; *Accu Chek*, *GlucoPlus*, *GlucoNavii*, *OneTouch Ultra Plus Flex* and *CareSens*, to have relatively stable mean glucose levels between glucometers and known laboratory glucose readings. There was a likelihood for CareSens not meeting the ISO 15179:2013 criteria while both Accu Chek and CareSens glucometers had higher coefficient of variation (CV) values of 77% and 56.5%, respectively.

Conclusions: This study highlights the variability in readings among glucometers with *GlucoPlus*, *GlucoNavii* and *OneTouch Plus*, showing a degree of reliability for patients' self-monitoring of random blood glucose levels. Thus, regular evaluation of glucometers remains key for their accuracy and patient management.

BACKGROUND

Diabetes mellitus is a chronic metabolic disease associated with raised blood glucose levels that occurs when the body cannot utilize produced insulin, or the pancreas cannot produce enough amounts of insulin, leading to microvascular and macrovascular complications.[1-3] Like other non-communicable diseases, the disease contributes to catastrophic out of pocket spending for patients.[4-6] In some countries, like the USA, where reliable data are available, diabetes alone has been responsible for USD 1 trillion dollars in health expenditure, which is about 338% increase in health costs over the last 17 years.[7] Nearly 527 million people in the world had diabetes claiming about 6.7 million deaths in the year 2024.[8] The latest (2025) IDF Diabetes Atlas[7] further reports 1 of 9 (11.1%) of the adult population aged 20-79 years to be living with diabetes, with over 4 in 10 unaware of having the disease.

There are two types of diabetes mellitus, type I and II. Type I also called insulin-dependent diabetes mellitus occurs when the pancreas produces little or no insulin thus requiring daily injection. Recent studies on global incidence, prevalence, and mortality of type I diabetes have revealed 8.4 million people to have type I diabetes worldwide predicting an increase in prevalent cases to 13·5-17·4 million by the year 2040.[9,10] The prevalence is relatively lower than previously reported in 2017,[11] although the prediction is alarming. In Tanzania, a systematic review of prevalence and incidence of type I reported a relatively low prevalence despite that the review based on the limited available evidence.[12] Type II Diabetes mellitus occurs when the body cannot effectively utilize insulin. It is the most common type occurring among adults with more than 90% of all diabetes cases in this group.[8,11]

Diabetes mellitus is the major cause of heart attack, stroke, kidney failure, blindness and lower limb amputation as consequential complications.[13]

Common diabetes symptoms include excessive thirst, frequent urination, extreme hunger, extreme body tiredness, unexplained weight loss, visual changes and tingling or numbness sensation on feet and hands. Lifestyle modifications like eating a healthy diet, avoiding tobacco, being physically active and maintaining a body weight within normal range (BMI 18-25 kg/m^2) have proven effective in preventing or delaying the onset of diabetes mellitus (type II).[13]

Diabetes mellitus is diagnosed based on the criteria established by the American Diabetes Association. A diabetic person will have the fasting blood glucose concentration greater than 126 mg/dl (7.0 mmol/l), or plasma glucose (OGTT) greater than 200 mg/dl (11.1 mmol/l) 2 hours postprandial. In addition, the random plasma glucose should be greater than 200gm/dl (11.1 mmol/l) plus symptoms of hyperglycemia, and glycated haemoglobin (HbA1C) greater than 6.5% (48 mmol/mol).[14] In diabetes, HbA1c levels are used to diagnose and monitor the disease and can be influenced by age, ethnicity, and haemoglobinopathies tending to slightly increase with age, even in people without diabetes.[15]

Tanzania is among five countries in sub-Saharan Africa with large number of diabetes cases of 2.8 million and mortality cases of 36,334 in 2021 and by 2030, about 4.2 million deaths among 20 to 79 year-old adults are estimated to be diagnosed with diabetes.[16,17] Early detection and management of diabetes can prevent complications and mortality related to poor management of diabetes. The major technological challenge that many sub-Saharan countries face is lack of early diagnosis and detection of diabetes complications, which leads to an increase in disease burden and its poor control.[18]

Among efforts taken globally to reduce the burden of the disease is self-monitoring of blood glucose (SMBG) that is done with glucometers, which are rapid, simple and affordable while requiring no highly trained staff, laboratory and minimal or no electricity.[19] With self-monitoring of blood glucose levels at home, patients with diabetes can maintain and achieve specific glycemic goals. In addition, it is possible to avoid severe hypoglycemia or hyperglycemia, detect and prevent hypoglycemia and hyperglycemia. All these enable an individual to identify a glucose profile that will best reveal trends in various situations while helping adjust to individual lifestyle. [20] This is important, particularly where healthcare providers are remote. Available reports on patients with type II diabetes attending secondary and tertiary healthcare facilities in Tanzania indicate 222 (67%) out of 330 diabetic patients owning Glucometers,[21] indicating a sense of awareness on self-monitoring at home among individuals. As it is understood, herd-controlled blood glucose through self-monitoring at home can reduce not only the burden of the disease, but also its consequences and economic costs to contain the disease from a broader perspective. In similar context, health expenditure of USD 966 billion globally is attributed to diabetes and estimated health budget consumption of 40% [8,22] reported in some countries may be reduced.

Glucometers give quick results of blood glucose and are therefore key in enabling the physician to make fast and appropriate actions to contain the disease in hospitals,[23] and recently, at home through self-glucose measurements. The major challenge on this approach is the potential of variability and inaccuracy of available glucometers with variable brand names. Inaccurate glucometers can lead to misjudgment of patient's real blood glucose status thereby impairing physicians' decisions in the treatment, which may harm the patient.[24] The glucometers are of different types according to manufacturers based on standard provided by the International Organization for Standardization (ISO-15197-2013).[25,26] Glucometers allow patients to check the impact of different treatments on blood glucose and adjust accordingly e.g. through insulin injection, complete the information provided by glycated haemoglobin and identify, quickly treat and prevent hypoglycemia or hyperglycemia.[27]

The availability of various glucometers with variable performances has made the need to have standard guidelines on the minimum requirements of glucometers. As such, organizations such as the American Diabetes Organization and International organization of standardization (ISO) have been developed to safeguard the concerned patients. The free-market conditions have widened chances for recent competition in both meter and strip technology due to the increasing number of manufacturers.[28,29] As a result, different glucometers with varying performances have been introduced, heightening the likelihood for production of glucometers that can compete in the market but with potentially substandard performance. Consequently, this can lead to greater variations of results compared to known laboratory standards.[30] Challenges in establishing glucometers' accuracy in recording blood glucose measurements have been previously reported,[31] and should be considered when discussing variability in glucometer results. This is critically, important in low- and middle-income countries where devices with potentially sub-optimal quality could be expected.[32]

Technically, the reasonable glucometer analytical error recommended by ISO 2013 between glucometers when used for patient glucose measurements should be within +/-0.83mmol/L of the laboratory blood glucose concentration when values are less than 5.5 mmol/L. Similarly, the allowable analytical error for the glucometer should be within +/- 15% for laboratory values above 5.5 mmol/L and ≤- 5% across all levels. Several factors influence the accuracy of glucometer values, including meter and strip technology, underlying conditions such as uric acids, changes in oxygen, hematocrit levels, environmental factors such as temperature, operator knowledge and performance technique.[33]

Tanzania has made efforts to control diabetes through the availability of diabetes clinics that provide education on diabetes complications and encourage the use of glucometers as a way of self-monitoring glucose levels, nutrition counselling and easy availability of equipment and drugs. Munyogwa et al. reported the prevalence of diabetes of 12.3% in Tanzania[12], a rate that might have increased due to poor quality of care in sub-Saharan Africa, as was earlier projected[18,34] and recently reported by Luambano et al.[35] The situation, compounded by variations of glucometers from different manufacturers, readings can lead to incorrect therapeutic interventions and complications such as hypoglycemia

or hyperglycemia, diabetic retinopathy, nephropathy and others.[36] Therefore, this study aimed to assess the performance of glucometers among diabetic patients who attended the Emergency Department at Muhimbili National Hospital, to provide reliable on-site information necessary for validating the accuracy of commonly used glucometers. The idea was to obtain glucometers with smallest deviation from each other that is accepted by the international organization for standardization.

METHODOLOGY

Study Design, Settings and Study Area

This was a cross-sectional study that was conducted from November 2022 to January 2023 to assess and compare the performance of Random Blood Glucose meters among diabetic patients at the Muhimbili National Hospital (MNH) Emergency Department in Dar es Salaam, Tanzania. The MNH is a Tertiary Hospital with 1,500 bed capacity with several departments. The Emergency Medicine Department (EMD) within MNH, is a full-capacity acute public emergency department, serving an average of 100 to 200 emergency patients per day (60,000 patients annually). As a public emergency department, the EMD receives both insured and non-insured patients, children and elders and people living within and outside Dar es Salaam city. The department provides different services, including medication, education on diabetes, blood glucose monitoring using both glucometers and laboratory glucose values, vitals, height and weight measurement for obesity assessment, since most of diabetic patients are brought to the emergency department because of diabetic complications such as diabetic ketoacidosis.

Study Population

The population for the study included diabetic patients aged 18 years old and above attending the Emergency Medicine Department with both Type 1 and Type 2 Diabetes. The most received age range in the EMD at MNH is generally around 35-54 years with an overall median age falling within the 30-50 range despite receiving some patients who are under 18. Patients with difficulty in accessing their veins for example patients with psychological status, pregnant women,[37] and patients who willingly refused to provide consent to participate in this study, were generously excluded without losing their right to receive medical service. Although, often no justification is required for exclusion but their inclusion,[37,38] pregnant women were excluded for convenience in their need for other medical attention. In addition, at MNH most cases of pregnancy are attended by the Obstetrics and Gynaecology Department than EM. Our study involved interviews via questionnaires, and similar findings could be obtained from other groups and be used by the universe. Otherwise, our study was non-invasive and the revised International Ethical Guidelines for Health-Related Research Involving Humans of the Council for International Organizations of Medical Sciences (CIOMS) applied.[38]

Sample Size

The sample size was calculated based on Cochran's formula by Cochran,[39] where the 95% confidence interval (95% CI) was set with level of significance of 5%. According to Kim et al.,[40] the proportion of glucometers that meet the ISO 15197:2013 for the accuracy criteria of standardization is 80%. With the set to 80% power of the test, the sample size was estimated to be 125 subjects to be recruited and provide reliable findings. Calculation for the sample size is shown below:

Formula: $n = Z^2P\ (100\text{-}P)/\varepsilon^2$

Where, n = sample size

Z= is the standard deviation, 1.96 corresponding to 95% confidence interval level

P= is the proportion of Glucometers that did not meet the ISO criteria of standardization

ε =margin of error, which is approximately 7%

Then, $n= (1.96)^2\ 0.8(1\text{-}0.8)/0.07^2 = 125$

Sample size being 125.

The minimum sample size was estimated to be 125 diabetic patients.

Common Glucometers

This study purposively evaluated glucometers that were commonly available and used to establish blood glucose status in Diabetic patients attending at MNH in the EMD. Glucometers with complete components such as a lancing device and test strips, were used to measure glucose levels in a total of 125 diabetic patients as per the estimated sample size.[17] These included the *Accu-Chek* (Roche Diagnostics USA, 9115 Hague Rd, Indianapolis, Indiana, 46256, United States), *Gluconavii* (SD Biosensor Inc., C-4&5Floor, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Republic of South Korea, *OneTouch Ultra Plus Flex* (Johnson & Johnson, 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, USA), *GlucoPlus* (GlucoPlus Inc., 2323 Halpern, Ville St-Laurent, Québec H4S 1S3, CANADA) and *CareSens* (i-SENS, Inc. Biosensor and Electrochemistry Technology, 57 Gwangun-ro, Nowon-gu, South Korea) glucometers.

Data Collection and Procedure

Informed consent was obtained from the participants, after which sociodemographic information such as age, sex, education level and economic level was gathered. Blood pressure of the patient and medications used were also recorded. Capillary blood glucose were obtained from the middle fingers of subjects by finger prick. Part of the blood was placed on the test strips of the glucometers and the readings recorded. The blood glucose monitoring was done by trained professionals to ensure accurate results provided that the environmental conditions were optimal. Venous blood samples were collected from a left antecubital fossa and placed in specific labeled ABG tubes and transported to the laboratory within 2 hours for blood glucose values reading.

Each participant was tested with each glucometer brand as aforementioned in the previous section. Measurements were taken for 5 days in a laboratory setting as components found in arterial blood gas (ABGs) at the Emergency Department with a controlled temperature and humidity, and the obtained glucometer values were compared. Blood samples were obtained from both finger

pricks and venous blood within five minutes apart. In the process, participants were asked to wash and dry their hands before samples were taken as required.

Validity and Reliability of Study tools

Data Management

This involved data collection, organization, storage and data backup. Prior to the main study, questionnaires were evaluated through base line pre-testing by FNC to ensure that they captured the relevant information needed. Pre-testing of questionnaires was done on some volunteering staff at the study site under the supervision of EVM. Demographic data collection was done through designed, pre-tested interview questionnaires (FNC). The laboratory findings and the questionnaires were kept in closed envelopes and then taken to recording centers. Data organization involved creating folders and naming files all of which were done using SPSS software in personal computers and external storage devices like flash disks and hard disks as backups. Data backup included making copies of original data to take care of any accidental data losses.

Data Analysis

The Statistical Package for the Social Sciences for Windows (version 20.0. SPSS Inc., Chicago, IL, USA) was used to enter, clean and analyze data. Social demographic characteristics were calculated and presented as means and standard deviations. Comparison of means was done using independent *t*-test. The mean readings of laboratory glucose values by different glucometers were presented as proportions complemented with mean differences and standard deviations at P=.05. The technical accuracy of different glucometer performances was evaluated through regression analysis and presented as percentage bias. The correlation of laboratory glucose levels by different types of glucometers was presented as Pearson's Ratios at P=0.05. The Bland Altman plots were used to show the agreement or disagreement between glucometer readings and Laboratory glucose reference readings.

Ethical Consideration

The approval of the study protocol was sought from Muhimbili University of Health and Allied Sciences Ethics Review Sub-Committee (Ethical Clearance Ref. No. DA.282/298/01L/). Informed consent was obtained from participants where confidentiality and privacy were observed and participant identification such as names were not included in the questionnaire to ensure confidentiality. Storage of the questionnaires after completion of the research activity in archives were in such a way that no unauthorized person could have access.

RESULTS

Socio-Demographic Characteristics of the Study Participants

Majority of the participants 59 (47.2%) were in the age range of 39-59 years old, with the mean age of 43.2±15.39 years (Table 1). A total of 69 (55.2%) of participants were females and 58 (46.4%) of all participants had at least secondary education while 18 (14.4%) had higher education. The economic status of the participants was such that 91 (72.8%) had medium earnings while 18 (14.4%) were low earners and 16 (12.8%) were high earners indicating that about 107 (85.6%) of participants' economic status was good. The distribution of participants based on the type of glucometer they used revealed that 9 (7.2%) used *Accu-Chek*, 26 (20.8%) *Gluconavii*, 10 (8.0%) *GlucoPlus*, and 2 (1.6%) *OneTouch Ultra Plus Flex*.

TABLE 1: Socio-Demographic Characteristics of Study Participants

Variable	Frequency (n)	Percent (%)
Age		
18-38	48	38.4
39-59	59	47.2
60-80	16	12.8
Above 80	2	1.6
Mean age in year	43.2±15.39	
Sex		
Male	56	44.8
Female	69	55.2
Education level		
Never went to school	10	8.0
Primary education	39	31.2
Secondary education	58	46.4
Higher institutions	18	14.4
Economic status		
Low	18	14.4
Medium	91	72.8
High	16	12.
Type of glucometer		
Accu-Chek	9	7.2
Gluconavii	26	20.8
GlucoPlus	10	8.0
OneTouch	2	1.6
CareSense	0	0
Had no glucometer at home	78	62.4

Possession of Glucometer at Home for Self-Blood Sugar Monitoring

The findings from this study show that out of 125 participants, 78 individuals (62.4%) had no glucometers at home (Table 1). For participants who owned glucometers at home, brands *Accu-Chek*, *Gluconavii*, *GlucoPlus*, and *OneTouch Ultra Plus Flex* were the most commonly owned glucometers among the participants, while none had *CareSens* in possession for self-blood glucose monitoring at home. In measuring blood glucose levels by different glucometers, the major finding from the study is that all of the glucometers, namely *Accu-Chek*, *GlucoPlus*, *Gluconavii*, *OneTouch Ultra Plus Flex*, and *CareSens*, showed relatively stable mean glucose levels with acceptable standard deviations (Table 2). The results are suggestive that glucometers have the potential to provide consistent and reliable measurements for diabetic patients. In addition, the study revealed a significant positive correlation between the laboratory glucose level readings obtained from various types of glucometers (*Accu-Chek*, *Gluconavii*, *GlucoPlus*, *OneTouch Ultra Plus Flex* and *CareSens*) (Table 2). The correlation coefficients ranged from moderate to very strong, suggesting that all the glucometer brands provided reasonably accurate estimations of blood glucose

levels. The results show statistically significant differences (P<.05) between the mean readings of the glucometers and the laboratory glucose values. *Accu-Chek*, *GlucoPlus*, *Gluconavii* had a positive statistical significance all of which exhibiting significant variations in their readings compared to the laboratory standard levels (p<.05) to each glucometer (Table 2).

The Technical Accuracy of Different Glucometer Performances Among Diabetic Patients

The *Accu-Chek* glucometer exhibited a slight negative bias, while *GlucoPlus*, *Gluconavii*, *OneTouch Ultra Plus Flex* and *CareSens* showed positive biases of varying magnitudes. Regression equations were derived for each glucometer, indicating the relationship between their readings and laboratory blood glucose values. Statistical analysis confirmed that there were significant associations between glucometer readings and blood glucose levels for all models except for *CareSens*, which had a marginal p value (p=.069) (Table 3).

The study revealed a significant positive correlation between the laboratory glucose level and the readings obtained from various types of glucometers, including *Accu-Chek, GlucoPlus, Gluconavii, OneTouch Ultra Plus Flex, and CareSens* (Table 4). The correlation coefficients ranged from moderate to very strong.

The results show statistically significant differences between the mean readings of the glucometers and the laboratory glucose values. *Accu-Chek*, *GlucoPlus*, *Gluconavii* had a positive statistical significance direction and all exhibited significant variations in their readings compared to the laboratory standard levels to each glucometer (p<.05) (Table 5).

Extent to Which the Glucometer Values Deviate from Laboratory Glucose Values

The Bland Altman graphs show the extent to which the glucometer values deviate or are close to the Laboratory glucose values (Figure 1). For the accurate results the glucometers readings have to be close to the reference values, however with the *Accu-Chek* it had 1 outlier that was in a positive region, showing there is a relative technical inaccuracy of the *Accu-Chek* glucometer compared to the reference range. On the other hand, the values for *CareSens* were scattered from the reference values, containing multiple outliers in both positive and negative regions, showing that such glucometer might not perfectly meet the ISO 15179:2013 criteria. Although this depends on multiple measurements to unequivocally disregard this glucometer for use.

The x-axis showing the mean glucose values of the glucometers and the y-axis showing the mean difference of glucometers and the laboratory glucose values (Figure 1).

The Clinical Accuracy of Different Glucometer Performances

This study revealed that *One Touch* device had the lowest coefficient of variation CV at 42.9%, suggesting better precision and potentially higher accuracy. The *GlucoPlus* and *Gluconavii* glucometers had CV values of 47.3% and 46.4%, respectively, indicating relatively similar performances but less precision of CV values of 77% and 56.5%, respectively, suggesting greater variability and potentially lower accuracy. The *Accu-Chek* readings were relatively closer to reference values compared with some outliers, making it technically not very accurate (Figure 2).

FIGURE 1: Bland Altman Plots Showing Agreement/ Disagreement of CareSens and Laboratory Glucose Reference Readings

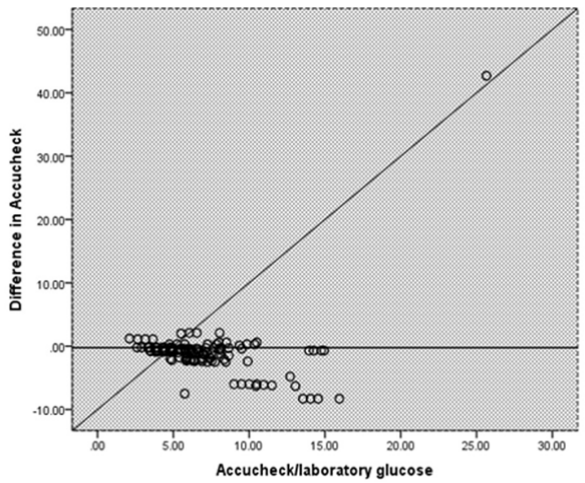

FIGURE 2: Bland Altman Plots Showing Agreement/ Disagreement of *Accu-Check* and Laboratory Glucose Reference Readings

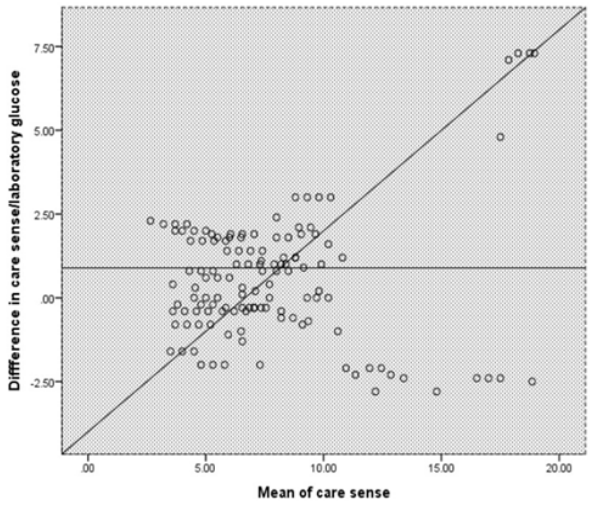

TABLE 2: Comparison of Performance of Various Glucometers Possessed at Home for Self-Blood Sugar Monitoring

Variable 1	Variable 2	Mean Differences	Standard deviation	*t*-value	*P* Values
Laboratory glucose	Accu-Chek	1.03040	4.50	2.56	.012
	GlucoPlus	0.54480	2.10	2.89	.004
	Gluconavii	0.31520	1.46	2.41	.017
	OneTouch	-0.37440	1.67	-2.51	.013
	CareSense	-0.54720	1.94	-3.16	.002

TABLE 3: Showing Technical Accuracy Parameters of Different Glucometers for Laboratory Blood Glucose Measurements

Type of Glucometer	Percentage Bias (%)	Regression Equation	*P* Value
Accu-Chek	-4.8845	Y=0.199X+0.266	.026
GlucoPlus	1.1529	Y=-0.380X-0.199	.001
Gluconavii	0.6310	Y=-0.511X-0.96	.001
OneTouch	11.5960	Y=-0.324X-0.121	.001
CareSense	11.3434	Y=-0.163+0.133	.069

TABLE 4: Correlation of Laboratory Glucose Level as Standard with Different Types of Glucometers

Variable 1	Variable 2	Pearson's Ratio	*P* Value
Laboratory glucose	Accu-Chek	0.389	.001
	GlucoPlus	0.819	.001
	GlucoNavii	0.926	.001
	OneTouch	0.891	.001
	CareSense	0.874	.001

TABLE 5: Differences Between Mean Readings of Laboratory Glucose Values and Different Types of Glucometers

Variable 1	Variable 2	Mean Differences	Standard Deviation	*t*-value	*P* Values
Laboratory glucose	Accu-Chek	1.03040	4.50	2.56	.012
	GlucoPlus	0.54480	2.10	2.89	.004
	Gluconavii	0.31520	1.46	2.41	.017
	OneTouch	-0.37440	1.67	-2.51	013
	CareSense	-0.54720	1.94	-3.16	002

DISCUSSION

Patients' Socio-demographic Characteristics

This study sought to assess the accuracy of performance of different glucometers among diabetic patients at Emergency Department at MNH. The findings obtained are expected to create a base for contribution to our usual management approach towards patients with Diabetes Mellitus. It is with no doubt that these findings provide information on the most accurate glucometer that can be used in our facilities for proper management of diabetic patients. Majority of participants had an age range of 39-59 years, with a mean age of 43.2+/-15.39, with higher proportion of the patients being females (55.2%) (Table 1). Similar proportion was reported previously in Tanzania with estimated female gender proportions of 57.3%.[21,41] While the proportions may paradoxically bias to women as more vulnerable to the disease, it may solely be due to differences in health seeking behavior between men and females. Compared to women, men are said to have poor health seeking behavior that may be influenced by various factors, including societal expectations, cultural norms, and individual perceptions of masculinity. [42,43] Thus, in a group of health seeking patients, women may always be higher in proportion than men in common practice.

Our findings show that 72 (57.6%) of participants had at least secondary education most having been reached secondary or tertiary education. Eight percent (8%) of participants had no formal education (Table 1). Reports on global and regional estimates and projections of diabetes-related health expenditure,[22] and that of clinical characteristics and health care in Tanzania,[21] indicate different proportions from the current study, the proportion being lower (1.5%) for participants with no formal education. The proportion of people with no formal education may pose a barrier to the knowledge required to use appropriate glucometers and the importance of using glucometers for self-monitoring of blood glucose. The findings of this study show that 37.6% of participants had glucometers for blood glucose self-monitoring at home. This is different from a study done at Mwanza,[21] which showed that 67% of participants owned blood glucometers for self-monitoring. This is because in our study, 18 (14.4%) of participants had low economic status, thereby unable to buy the relatively high-priced glucometers. In addition, the proportion (8%) of participants with no formal education might however, have contributed to the low numbers of participants with no glucometers although it may depend on the differences in study groups and setting. For example, the current study was carried out in the Emergency Medicine Department (EMD) of the National Hospital of which the patients might be quite different from those in common attendance at the three selected healthcare facilities in Mwanza. The Munyowa et al. study,[21] on the other hand, was carried out at the tertiary-level or lower healthcare facilities, of which health services might be different from those in EMD. We could also compare the difference in economic status of participants, but this cannot be done as the study in Mwanza did not assess the economic status of participants. In our study, the most common used glucometer for self-monitoring of blood glucose by participants was *Gluconavii* (20.8%) followed by *GlucoPlus* (8%) while none of the patients owned the *CareSens* glucometer. The diverse possession of glucometers by participants could be attributed to price differences, but also commonness of the glucometers in the market.

Glucose Levels and Recorded Values of Different Glucometers

The recorded mean differences for the studied glucometers were 6.5+/- 4.4, (*Accu-Chek*), 6.9+/-2.9 (*GlucoPlus*), 7.2+/-2.9 (*Gluconavii*), 7.9+/-3.1 (*OneTouch Ultra Plus Flex*) and 8.1+/-4.0 (*CareSens*).

These findings reflect that the studied glucometers had stable mean glucose levels falling within acceptable standard deviation, thus being reliable for recommendation to continued use by diabetic patients for self-monitoring of blood glucose. In that way, if proper self-blood glucose monitoring is ensured at home level, early warning signs of development of complications can be noticed and reported for proper management and medical attention to prevent the anticipated complications resulting from uncontrolled blood glucose levels.

The study findings show significant and positive correlation between the reference laboratory glucose levels and the glucometer readings (P=.001), showing that all glucometers provide reasonably accurate estimations of blood glucose levels. This means that the glucometers obey the ISO Criteria 15197; 2013. The correlation coefficient, r was 0.389, 0.819, 0.926, 0.891, 0.874 for *Accu-Chek*, *GlucoPlus*, *Gluconavii*, *OneTouch Ultra Plus Flex* and *CareSens*, respectively (Table 4). The range of correlations from moderate to strong are suggestive that all the glucometer brands provide reasonably accurate estimations of blood glucose levels. This reflects high possibility that the glucometers that were studied can produce accurate readings of blood glucose in patients (P=.001). This is critically important as control of glucose levels and monitoring depends much on the accurate measurement readings. The findings are concordant with previously reported findings from the study conducted in the period of 2009 – 2011 in Germany [44] in which 34 glucometers had a significant correlation with that of the reference glucose values.

The findings of this study show that there is a significant difference between the mean readings of the glucometers and the laboratory glucose values, with the *Accu-Chek*, *GlucoPlus* and *Gluconavii* having a positive significant direction, their P values being 0.012, 0., 0.004 and 0.017 respectively, and *OneTouch Ultra Plus Flex* and *CareSens* having a negative direction of their mean differences and their variations. This contrasts with the findings by Dahman et al.[45] which showed no significant difference in blood glucose levels from glucometers when compared with that of the laboratory average values.

Technical Accuracy of Different Glucometers Performances

Linear regression equations were used to establish the potential relationship between test readings and laboratory blood glucose values. *GlucoPlus*, *Gluconavii*, and *OneTouch Ultra Plus Flex* had positive percentage bias indicating that their glucose values were slightly overestimated from the reference glucose values (P<.05). This helps us to evaluate the accuracy of the test readings

when compared to the laboratory values which is critical in quality control of our tests. Increasing bias can lead to misdiagnosis of diseases and can dramatically impair the diagnostic power of laboratory tests.[46] Nevertheless, the difference in glucose readings between *CareSens* glucometer and that of laboratory glucose values were marginally significant (P=.069) providing a room to recommend the test for use. On the other hand, *Accu-Chek* readings had a negative percentage bias of -4.8845, reflecting that its glucose readings have been underestimated from the laboratory glucose values, the deviation from the laboratory glucose levels being significant (P<.05). The finding is in agreement with Chouken and company findings[24], which showed a significantly positive mean bias of 13.8% and 29.1% for *One Touch Plus* and *CareSens*, respectively, indicative that the ISO 15197:2013 were met.

The Bland-Altman graphs (Figures 1 and 2) showed that glucometer glucose values were close to the reference glucose values. Exceptions are the *Accu-Chek*, which had one outlier in a positive region, and *CareSens* that had its glucose values scattered from the reference value and many outliers in both positive and negative regions (Figures 1 and 2). In this context, *GlucoPlus*, *Gluconavii* and *OneTouch Ultra Plus Flex* were technically accurate and for the *Accu-Chek* and *CareSens* had no technical accuracy. Such variations in technical accuracy may be attributed to examiners' characteristics, environmental factors such as temperature and humidity and whether glucometer is too old or broken.[47] Similar findings were reported by Freckmann and team,[44] which showed that *Accu-Chek*, *Code Free* and *MyLife* Glucometers not meeting the ISO 15197:2013 standards due to possession of varying number of outliers.

The Clinical Variability of Different Glucometer Measurements

The study findings showed that *GlucoPlus* and *Gluconavii* had coefficient of variations (CV) of 47.3% and 46.4%, respectively, showing relatively similar performance. *OneTouch Ultra Plus Flex*, on the other had relatively lower coefficient of variation of 42.9% suggestive of potentially lower precision despite potentially higher accuracy. The findings revealed *Accu-Chek* to have the highest coefficient of variation of 77% followed by *CareSens* with coefficient variation of 56.5% indicating greater variability and therefore, lower accuracy. This was the driving force for the idea to conduct this study. In real practice the glucometers provide variable results which have as well, been reflected in this study. Such variable performances may influence control and management of diabetes particularly in those self-testing at home.[48] In one self-monitoring of blood glucose levels,[49] accuracy of instrument is key as it determines the use, non-use of medication or even taking immediate measures to rescue one's life where necessary. Studies on adherence have emphasized the need for customized interventions to improve self-management education and support, particularly for older adults.[49,50]

As highlighted in the preceding paragraph, this study enlightens on the potential clinical implications of variability in glucose measuring devices to diabetic patients as their self-testing at home guides medication to alleviate the disease situation. A tool that lacks accuracy with low precision, specificity and sensitivity will always cause harm to the patient. Future research should include regular re-evaluation of the commonly and newly deployed devices for accuracy on the intended purpose to serve life of diabetic patients.

Limitations

This study was done as part of elective student (FNC) research which had a short timeframe. This necessitates for a large study in a long period of time, that can accommodate bigger large number and evaluation of several issues in diabetic patients, some of which could be patient focused (Patient Centred Outcome Research). In such cases patient can share their experience to determine the best approach for blood sugar monitoring and in determining medication which are genuinely critical for blood sugar control.

CONCLUSION

This study sought to assess the performance of different glucometers among diabetic patients attending at Emergency Medicine Department at MNH. The idea was to create a base for best use of glucometers with greater accuracy for monitoring glucose in patients to recommend to practicing physicians. The study found many diabetic patients with no glucometers for self-monitoring of blood glucose at home. Consequently, poor glucose control and high potential for increased diabetes related complications. The most common reason for non-possession of glucometers for self-monitoring of blood sugars at home were low economic status thus inability to afford the glucometer prices. The findings that *GlucoPlus*, *Gluconavii*, *Accu-Chek*, *OneTouch Ultra Plus Flex* and *Caresense* had blood sugar values which are close to each other endorses their reliability as useful devices to alternatively be used by diabetic patients for blood glucose self-monitoring at home. Nevertheless, it can unequivocally be advised that, *GlucoPlus*, *GlucoNavii* and *OneTouch Utra Plus Flex*, due to the noted accuracy, and reliability be used in health facilities unlike the *Accu-Chek* and *CareSens* that showed lower accuracy.

Recommendation

This study recommends advocacy on self-monitoring of blood sugar at home for effective management and control in diabetic patients. Emphasis should be on the importance of using glucometers at home for self-monitoring of blood sugar in patients with the use of most reliable and accurate available glucometers on time and space. To safeguard diabetic patients, policy makers are urged to include regular re-valuation of glucose monitoring tools such as glucometers which variably influence diabetic patients' survival. This will enable selection of only reliable devices which would mean patients starts with accuracy from self-tests at home to later complement clinical evaluation by physicians.

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