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EVALUATING A GLUCOMETER'S PERFORMANCE BY TESTING ITS RELIABILITY AND VALIDITY AT THEARMED FORCES HOSPITAL JAZAN, SAUDI ARABIA

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ABSTRACT

***Background*:** Glucometers are small, fast, and easy to operate devices used to monitor hypoglycemic and hyperglycemic disorders. Glucometer accuracy is influenced by multiple factors, and quality control tests can be used to ensure proper glucometer functioning, matching the glucometer's readings with those of a reference chemistry laboratory analyzer. ***Objective*:** To evaluate the performance of a glucometer used in Armed Forces Hospital Jazan (AFHJ) in the hands of trained operators under optimal operating conditions. *Method*: This analytical cross-sectional study was conducted at Armed Forces Hospital, Jazan (AFHJ), Kingdom of Saudi Arabia (KSA) on August 2021. Fingertip capillary blood and extracted blood from 200 randomly selected adult participants(age was >18 years) were tested using a glucometer (ONE TOUCH Select Plus Flex) and a reference chemistry analyzer (Cobas e 501, Roche). ***Results*:** The coefficient of variation(CV) of the first glucometer fingertip glucose readings (CV = 35.34) was similar to that of the second glucometer fingertip glucose readings (CV= 35.33). Approximately87% of the first glucometer readings were within ±15 mg/dl of the reference value for glucose concentrations below 100 mg/dl. Around98% of the results were within ±15% of the reference value for glucose concentrations 100 mg/dl or higher. ***Conclusion*:** The assay of capillary blood glucose by the ONE TOUCH Select Plus Flex had high precision for all glucose levels and high accuracy for those with high glucose levels (≥100 mg/dl).

***KEYWORDS*:** Blood glucose, glucometer (ONE TOUCH Select Plus Flex),reliability, validity, precision, accuracy, diabetes, KSA.

BACKGROUND

The number of individuals with diabetes has increased sharply, making it one of the major chronic diseases that need special care. Without monitoring blood glucose levels in such individuals, many complications might occur, causing gradual deterioration to most of the human body systems and functions. Therefore, having a small, fast, and easily operate device is one of the major characteristics of the glucometer as a monitoring tool for both hypoglycemic and hyperglycemic disorders. Glucometers were first developed as a self-monitoring tool for blood glucose, but now they are widely used in clinical settings, such as emergency rooms, ICUs, clinics, and ambulances, as well as ships, cruises, and many other places. The first glucose self-monitoring system (glucometer) was developed by Anton H. Clemens in 1970 and intended for physician office use.[1]

Glucometers have two major parts, the detection part (glucometer) and the reaction part (test strips). These strips contain glucose oxidase, which is an enzyme that reacts with a patient's blood glucose, then the electric current generated by this reaction is detected by the glucometer. The number in the glucometer readout corresponds to the electrical current strength, which indicates the concentration of glucose inablood sample. The glucose reading is demonstrated as milligrams per deciliter (mg/dl) or millimoles per liter (mmol/l).[2]

The accuracy of the glucometer is influenced by the user'sability to use it properly. There are many reasons that contribute to wide variations in glucometer readings, including unclean hands, dirty glucometers, inadequate amount of blood, bubbles, clots, alcohol contamination, and applying much pressure on strips that break the connection between the receiving part and the testing part. The test strips and glucometer must be stored at room temperature, avoiding minus temperature and hot temperature as it will affect the accuracy of testing. Never store test strips and glucometer in high humidity areas asthekitchen because humidity affects the accuracy of the test, so always seal the strip container after taking out the strip, and the strip taken from the container must be used within 3 min of removal. An error can also occur if mobile phones are nearby because mobile emits radiation, so, the mobile phone should be away at least half a meter from glucometers.[1,3-4] Plasma glucose is 10–12% higher compared to whole blood. Blood sample handling and analysis timing greatly influence the accuracy of the test. If the sample analysis is delayed, a blood glucose level would be falsely lower, and to avoid such an issue, the blood should be separated from cells immediately (within 30 min) and refrigerated until analysis.[2]

According to clinical and laboratory standards institute (CLSI), at abnormal blood glucose levels (>100 mg/dl), a difference in glucose measurement between glucometer and reference chemistry laboratory analyzers should not exceed ±20%, and at a blood glucose level of <100 mg/dl, the difference should be ±15 mg/dl or less. The Food and Drug Administration (FDA) requires accuracy requirements almost like those of CLSI. However, a standard of variation of <5% of reference values was proposed by the American Diabetes Association (ADA), but unfortunately, this is not achieved yet. At abnormal glucose levels, the variation is expected more; but the variations are insignificant when the glucose level is normal. If the measurement error of glucometers is less than 5%, they would be an alternative to the reference chemistry laboratory analyzers. Proper knowledge of physicians plays a major role in interpreting the accuracy of test results.[2,5-7]

There are two quality control tests that can be used to ensure that your glucometer is working properly. These tests are recommended for the new glucometer when you open a new test strips container or when you get unusual results. The first quality testing can be carried out using a liquid control solution instead of finger blood, and suchasolution can be bought from pharmacies. The second quality testing is matching the glucometer readings with reference chemistry laboratory analyzer results.[8]

Salacinski (2014) suggested that the glucometer provided poor validity and reliability results compared to the reference chemistry laboratory analyzer results and recommended that the glucometers should be used for patient management, but not for the diagnosis, treatment, or research purposes.[9]

Here we hypothesize that there would be significant variations between glucometer measurement and the reference chemistry laboratory analyzer regarding blood glucose level testing.The design of our study is an analytical cross-sectional study. Ethically approved consent was obtained from the research ethics committee in the study area. To our knowledge, no similar studies were conducted at the local or national level to study the validity of glucometer used in clinical settings.Therefore, the aim of this glucometer evaluation was to test the accuracy and reliability of the glucometer used in Armed Forces Hospital Jazan (AFHJ) in the hands of trained operators under optimal operating conditions.

RESEARCH METHODOLOGY

A. Study Design and Area

This analytical cross-sectional study was performed at Armed Forces Hospital Jazan (AFHJ), Jazan, Saudi Arabia on August 2021. Jazan is the capital city of the Jazan region that lies in the southwest corner of Saudi Arabia on the Red Sea coast, just north of Yemen and has a large agricultural community. The AFHJ is a 70-bed secondary hospital that provides health care for military personnel and their families.

B. Study Population

The study population was the outpatients who visited the phlebotomy area in the outpatient building for blood glucose testing and/or other ordered investigations, and samples were collected from them.A sample size of 200 was calculated from the study population,[10] and a systematic random sampling method was used in which every third patient, according to their order of attendance at the phlebotomy area, was included in the study. The inclusion criteria were:age ≥ 18 years, eligibility for medical care in AFHJ, and blood samples should be withdrawn for conducting pre-ordered blood lab-workup by the hospital physicians. The exclusion criteria included those for whom the study procedures would not be feasible due to severe dementia, history suggestive of mental retardation, or unstable medical condition.

C. Sample Collection

First, the phlebotomist introduced himself to the contributor and asked her/him to have a seat and told her/him about the purpose of testing blood glucose using a glucometer as well as blood extraction to gain patient consent to participate. Next, the contributor is asked about his/her name and ID number.The phlebotomist then prepared the equipment and the puncture site in the patient arms then performed the venipuncture. The collected sample was filled in the plain yellow-topped tube. The collected yellow top tube was labeled at the extraction area. Then,fingertip capillary blood glucose level was measured twice using a glucometer by pricking the patient fingertips, then one drop of fingertip blood was added to the glucometer test strip. Next, plain

yellow-topped tube samples were sent to the chemistry laboratory for chemistry tests analysis, including serum glucose test as well as measuring serum glucose using a glucometer.

D. Study Tools

1) Analysis of Capillary Fingertips Blood Glucose Level Using Glucometer

Patient fingertips were washed with soap and water and dried, then pricked.The first drop was selected for capillary blood glucose assay by the glucometer. However, if the hand-washing was not possible, the first drop was discarded, and the second drop was taken for the glucometer assy. The blood drop was used immediately for the glucometer assay (within 20 s).[2] The manufacturer instructions of ONE TOUCH Select Plus Flex glucometer were followed strictly during the Glucometer capillary blood glucose measurement.

2) Analysis of Blood Glucose Using Reference Chemistry Analyzer (Cobas e 501, Roche)

Since the blood samples had been clotted, all the yellow-topped tubes were centrifuged to separate the serum from whole blood. The serum was then pipetted using Pasteur pipettes and poured into the sample cups of the analyzer. Each sample was put in a known position in the sample rack of the machine, then the samples' information (patient numbers and names) were entered in analyzer software, and the racks were loaded into the analyzer. While awaiting for the results from the chemistry analyzer, the serum glucose of all tested samples was measured using a glucometer, and the results were recorded. Finally, the results from the chemistry analyzer were collected and recorded.

3) Data Collection

For each subject, a total of four glucose test readings results were obtained and recorded. Each fingerstick sample was tested using a glucometer with duplicate readings named as first and second glucometer readings per subject. Immediately after applying the blood to the ONE TOUCH Select Plus Flex glucometer, approximately 3 to 5 ml of additional blood was collected from the subject via venipuncture into a yellow top tube for testing serum glucose level using both glucometer and Cobas e501 Roche chemistry analyzer.

E. Ethical Consideration

Ethical approval was obtained from Research Ethics Committee in the study area, and all included subjects gave their informed consent prior to participation.

F. Statistical Analysis of Collected Data

Management of collected data was carried out using Microsoft Excel 2016. The statistical analysis was carried out using Statistical Package for Social Science (SPSS) version 22. A groupt-test was used in this study, as well as Pearson's correlation analysis and multiple linear regression analysis.

RESULTS

A. Demographics of the Included Subjects

The study included blood samples from 200 OPD patients, 102 males and 98 females. The baseline characteristics were not significantly different between males and females **(Table 1)**.

Table 1: Comparison between males and females regarding age and baseline biochemical findings (n= 200).

	Males▲ (n= 102)	Females▲ (n= 98)	T-value♣	P
Age (years)	38.4(13.8)	34.8(13.6)	1.838	0.068
First glucometer fingertips' glucose reading (mg/dl)	120.8(69.1)	120.5(72.7)	0.028	0.977
Second glucometer fingertips' glucose reading (mg/dl)	121.5(69.2)	121.4(72.5)	0.016	0.987
Serum glucose readings by Cobas e501 Roche chemistry analyzer (mg/dl)	127.3(71.1)	127.8(75.1)	0.049	0.961

▲: Mean and standarddeviation in parentheses, ♣: Group t-test.

B. Standard Deviations and Coefficients of Variations of Different Glucose Measurement

The Standard deviations and coefficients of variations (CV) were conducted and illustrated in **(Table 2)**. The CV of the first glucometer fingertips' glucose readings(35.34) was similar to that of the second glucometer fingertips' glucose readings(35.33). The CV of serum glucose readings using a glucometer (36.37) was similar to that of the serum glucose readings using Cobas e501 Rochechemistry analyzer(36.46). Also, the test-retest reliability was conducted by Pearson's correlation analysis with a highly significant correlation coefficient (*r*, 1.000 and P, 0.000). Therefore, the glucometer readings are highly reliable **(Figure 1)**.

Table 2: Coefficient of variation of different glucose measurements among the study group(n= 200).

	Minimum	Maximum	Mean	SD▲	CV (RSD)
Age	18.00	73.00	36.6	13.8	6.9
First fingertips' glucometer glucose reading ♣	70.00	502.00	1.2	70.7	35.34
Second fingertips' glucometer glucose reading♣	69.00	506.00	1.2	70.66	35.33
Serum glucose readings using glucometer♣	69.00	499.00	1.23	72.74	36.37
Serum glucose readings using Cobas e501 Roche chemistry analyzer♣	70.00	495.00	1.28	72.89	36.46

▲SD: Standard deviation, ♣: mg/dl; CV: Coefficient of variation and RSD: Residual standard deviation.

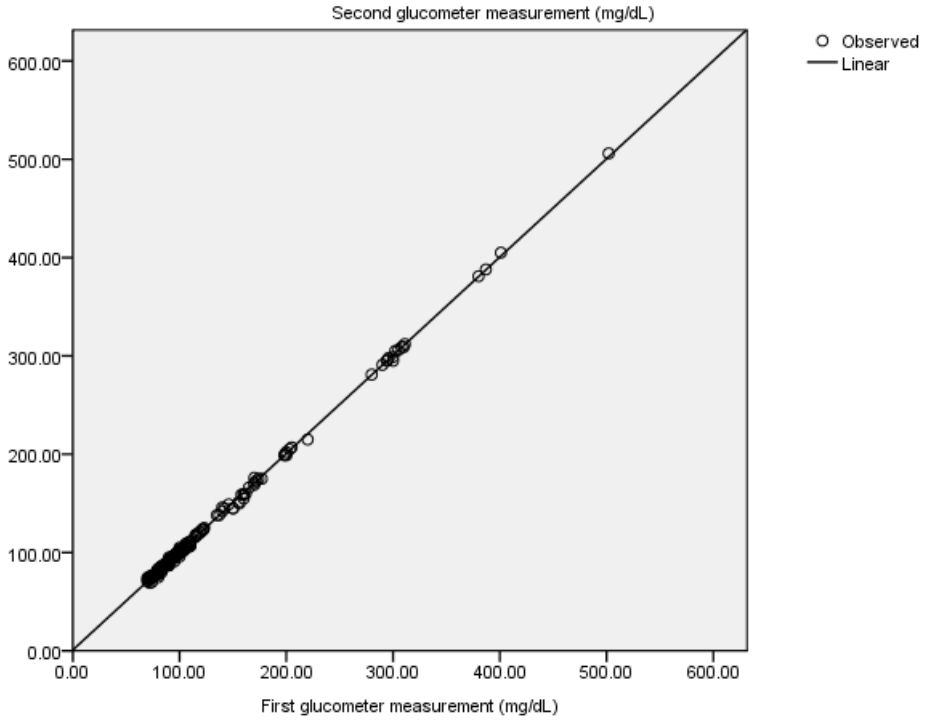

Figure 1: The relationship between the different glucometer measurements of capillary blood glucose (r, 1.0; P, 0.000)

C. Accuracy Evaluation

Accuracy was evaluated using ISO 15197:2013 criteria and by calculating the percentage of glucometer results falling within ±15 mg/dl (±0.83 mmol/liter) of the reference value for glucose concentrations below 100 mg/dl (5.6 mmol/liter) or within ±15% of the reference value for glucose concentrations at 100 mg/dl (5.6 mmol/liter) or higher.

The study group was classified into two groups according to the glucometer glucose levels in the first glucometer fingertips glucose readings. The first group had glucose level below 100 mg/dl (n = 117) and the second group above 100 mg/dl (n= 83) **(Table 3)**.

When grouped according to glucose levels below or above 100 mg/dl, 87.2% of results fell within ±15 mg/dl of the reference value for glucose concentrations below 100 mg/dl, and 98.2% of results fell within ±15% of the reference value for glucose concentrations 100 mg/dl or higher**(Table 4)**.Therefore, the glucometer is more accurate (98.2%) if the glucose level is ≥100 mg/dl.

Table 3: Distribution of the study group according to the first glucometer fingertips glucose levels.

	Number of Glucometer Readings	Mean	SD
<100 mg/dl	117	84.5	7.7
≥100 mg/dl	83	171.7	86.9

Group t-value = 10.8. P-value = 0.000.

Table 4: Percentage of glucometer results falling within ±15% of the reference value for glucose concentrations 100 mg/dl or higher and within ±15 mg/dl of the reference value for glucose concentrations below 100 mg/dl.

	N▲	Percentage of Readings within ISO Target Criteria♣
Glucometer Reading <100 mg/dl	117/200(58.5)	98.2
Glucometer Reading ≥100 mg/dl	83/200 (41.5)	87.2

N: Number of glucometer readings withthepercentage in parentheses, ♣: Percentage of glucometer readings within the ISO target criteria (±15% of the reference value for glucose concentrations ≥100 100 mg/dl and within ±15 mg/dl of the reference value for glucose concentrations below 100 mg/dl).

D. Association Between Glucometer Glucose Levels and the Serum Glucose Levels Assayed Using Reference Chemistry Analyzer (Cobas e501 Roche)

The Pearson Correlation revealed a highly significant linear association between glucometer glucose levels and the serum glucose levels assayed using Cobas e501 Roche reference chemistry analyzer (r, 0.992; P, 0.000). Also, the regression analysis revealed similar results **(Figure 2)**.

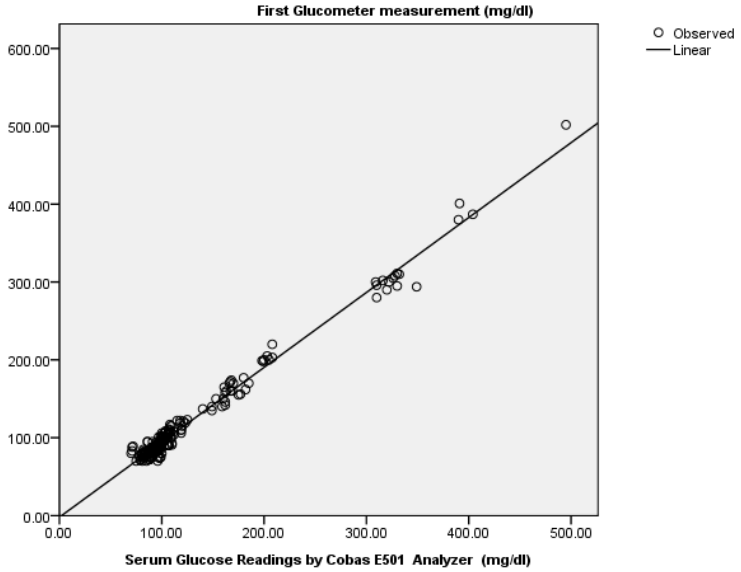

Fig. 2: Regression line: relationship between plasma auto-analyzer glucose and glucometer capillary blood glucose levels

R Square, 0.984; P, 0.000

DISCUSSION

Our data show that the tested glucometer (used at AFHJ) provided good validity and reliability results compared to the reference chemistry analyzer. On the other hand, Salacinski (2014) suggested that their Bayer Contour glucometer provided poor validity and reliability results than the reference chemistry laboratory analyzer results.[9]

Most (87.2%) of results fell within ±15 mg/dl of the reference value for glucose concentrations below 100 mg/dl, and 98.2% of results fell within ±15% of the reference value for glucose concentrations 100 mg/dl or higher. Therefore, the glucometer is more accurate (98.2%) if the glucose level is ≥100 mg/dl. In contrast,Harrison and colleagues found that around 99.3% of the glucometer results were within International Standardization of Organization (ISO) criteria (±15% of the reference value for glucose concentrations ≥100 100 mg/dl and within ±15 mg/dl of the reference value for glucose concentrations below 100 mg/dl). They also showed that under controlled conditions and supplies, around 99% of all readings of the Bayer Contour glucometer were within 15% of their reference chemistry laboratory analyzer.[11]

CONCLUSION AND RECOMMENDATIONS

Based on our results, we conclude that there was no significant difference between the glucometer readings and the chemistry analyzer.We conclude that the tested glucometer is reliable;the differences between the readings were narrow,so we can rely on the reading of glucometer in the monitoring of patients at the study site. But we advise that the glucometer should not be used in the main laboratory because usually the glucose test is not ordered alone but requested with another panel of

tests, then the chemistry analyzer is going to be much better at doing all that tests together. The glucometer is a fantastic device in diabetic clinics and emergency room (ER) departments because, in these areas, you need results rapidly, and using such a device will not take a long time. Thus, it is atime-saving tool, especially for diabetic patients. Sometimes you need to have results fast, as in diabetic ketoacidosis (DKA) or hypoglycemia due to insulin overdose.

The results of the present study indicate that the glucometer results were highly reliable, with high test-retest reliability and similar coefficient of variations in repeated glucometer measurement. Based on these findings, we conclude that the tested glucometer was highly precise in capillary blood glucose measurement.

Also, the accuracy of the glucometer was high, especially for those with glucose levels equal to or more than 100 mg/dl. The health care providers should be aware of the accuracy and precision figures of the glucometer in patients' management. The researchers had conducted plasma glucose in the laboratory using the autoanalyzer as a gold standard test for comparison. Based on the results of the present study, the glucometer is not a substitute for the analyzer in the hospital's main laboratory.

The result of this study will help to assure the treating physicians regarding glucometer result. Also, to get reliable results, it is important to increase operators' awareness about the proper use of such devices.

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