

Accuracy and Precision of Measured Blood Sugar Values by Three Glucometers Compared to the Standard Technique

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ABSTRACT

Introduction: The prevalence of diabetes mellitus has magnified, globally. Being cost effective and user friendly, using the glucometer systems has become more widespread. However, despite their advantages, there are controversies regarding their accuracy and precision.

Aim: To determine the accuracy and precision of the common glucometers of Bionime, Accu-check, and Beurer compared with the laboratory technique.

Materials and Methods: In a cross-sectional study, 257 patients of a general internal unit of Imam Reza hospital of Kermanshah were recruited. The blood sample of the subjects was transferred to the laboratory, then, two samples of capillary blood were tested by the three glucometers. The data was

entered into a checklist, then entered to SPSS-16.0 software, and analyzed by descriptive and inferential statistics.

Results: In this study, there was a positive correlation between the three blood glucose measurement methods with the standard approach, significantly, which indicates acceptable accuracy. However, this correlation was higher in the Beurer Glucometer ($r=0.976$, $p<0.001$). There were no significant differences in repeated measurements of blood glucose in the glucometers of Beurer ($t=0.96$, $p=0.92$), and Bionime ($t=0.50$, $p=0.61$) by paired t-test, but this test was significant for Accu-check system ($t=2.7$, $p=0.006$).

Conclusion: With respect to the acceptable accuracy and precision of Beurer and Bionime glucometers, it is suggested to use these methods for diabetic patients at homes as well as in the hospital units.

Keywords: Blood glucose self-monitoring, Diabetes complications, Diabetes mellitus

INTRODUCTION

Diabetes is one of the most common chronic diseases, worldwide. Increasing mean age of the population, urbanization, obesity and sedentary lifestyle, are the main risk factors of diabetes in recent decades. Over 285 million people suffered from diabetes in 2010, this has raised to 347 million in 2013 [1,2]. About 5% of Iranian (4 million people) has been affected by diabetes, which is anticipated to reach 6.8% in 2025 [3].

Diabetes causes premature death due to its complications such as cardiovascular disorders, blindness, nephropathy, and limb amputation; furthermore, these would impose additional costs on the families, community and also the health care system [4]. In a study in 2013, the cost of therapeutics care for a diabetic patient was estimated to be about 40.41\$, monthly [5]. Javanbakht M et al., presented the annual burden of diabetes as 3.78 million dollars in Iran [6].

Now-a-days, regarding the importance of diabetic patients management, the approach of "Self-Monitoring of Blood Glucose" (SMBG) has been suggested by the researchers in order to reduce the burden and increase the cost-effectiveness [7,8]. SMBG is a process of Blood Glucose (BG) checking by the patient himself, employing a glucometer device. It leads to increasing the participation of patients in their therapeutic process, as the result, promoting the quality of life through increasing their self-confidence [9,10]. According to the American Diabetes Association, SMBG commonly applied three times a day [11].

The awareness of diabetic patients about advantages of SMBG has risen, so, its uses have increased by 250% during the last 12 recent years [12]. The glucometer devices that are available in the market, have some issues regarding their standardization as well as their credibility to check BG. Diabetic patients generally rely on the

SMBG measurements for their medications. The advantages of the glucometers include; need of a small blood sample, simple utilization and cost effectiveness, however, the precision and accuracy of the devices are doubtful [13]. In this regard, Center for Disease Control (CDC) and prevention has determined an expected error of ± 20 mg/dl for $BG < 100$ mg, and $\pm 20\%$ for $BG > 100$ mg [13]. Accordingly, some of the glucometer devices overestimate the BG values; this makes it difficult to take the best clinical decision by health care workers [14].

Regarding the popularity of glucometer devices since 1980, many researchers demonstrated various credibility for the glucometers [15], in this regard, some shortcomings have been raised about glucometers accuracy and precision in fourth International Congress of SMBG application in 2011 [16]. The accuracy and precision are affected by many factors, e.g., sampling faults, non-calibration of the devices, body temperature, vasodepressor medications, oedema and haematocrit [17-20]. Bastan HM et al., affirmed the accuracy and precision of three glucometers devices; Glucocare, GlucoMen, and Glucotrend 2, with correlation of 95-97% to the standard procedure [21]. However, in the study by Ribeiro Gama MP et al., three other glucometers; Optium Xceed, MediSense, and One Touch Sure Step had not acceptable accuracy [22]. Moreover, in the study by Critchell CD et al., where capillary BG of critical care patients had been investigated, the adequate accuracy and precision were not achieved to Accu-check glucometer [23].

There are three common glucometers in the hospitals affiliated to Kermanshah University of Medical Sciences (KUMS) including Beurer, Bionime and Accu-check. This study was conducted for determining the accuracy and precision of the mentioned glucometers in comparison with the laboratory standard method.

MATERIALS AND METHODS

This descriptive-analytical study was done in 2014. The subjects were patients who were admitted to the internal units of Imam Reza (AS) Hospital of Kermanshah-Iran. By convenience sampling method 257 individuals were recruited. Sample size was estimated based on the study of Suresh KP et al., and via a special formula [24], Alpha of 5%, and the confidence coefficient of 95% [7]. Of 257, 141 people were diabetic (to determine the sensitivity) and 116 non-diabetic (for determining the specificity).

The sampling lasted about three months from February 2014 to April 2014. Inclusion criteria was; being conscious, willing to participate in the study, fasting for at least eight hours, haematocrit between 20%-60% based on the routine examinations (noted in the glucometers brochures), systolic BP higher than 100 mmHg, having normal cholesterol based on the previous examinations and history (less than 200 mg/dl), no breastfeeding among the female patients, having no coagulopathy disorders (based on the patients history), older than 18 years, not taking any vasoconstrictor agents e.g., epinephrine and dopamine, and have no intravenous line in the right hand. The patients whose blood samples were haemolyzed (according to laboratory reports) were excluded from the study.

Instrument

The instrument was a demographic information form which included the variables of age, sex, marital status, literacy level, profession, values measured by three glucometers and BG via the laboratory standard approach (902 Autoanalyser systems, manufactured by Hitachi Japanese Company). The Glucometer devices were GL40 Beurer, Accu-chek active, made in Germany and Bionime GM 110 glucometer made in Switzerland. The glucometer devices are verified by the American Diabetes Association (ADA), Committee Europe (CCE) organization, and health ministry of Iran. The stability was addressed by measuring 10 blood samples, twice for each subject, by the glucometers. The correlation between them was determined, in which, the glucometers of Bionime and Accu-chek had $r=0.96$ and for Beurer, $r=0.97$ were achieved.

The validity of the Autoanalyzer system of Hitachi 902 was confirmed through introducing the standard blood samples in range of low, high and normal every morning, before commencing the test of blood samples of patients, also its calibration was addressed by checking the system using a solution namely "control serum", daily. The test-retest method was used to check stability, in which, the blood sample was taken from five patients, each twice, for examining the BG, and the correlation between them indicated high reliability ($r=0.97$).

Sampling

For sampling, permission was taken from the research deputy of KUMS. The objectives of the study were explained to the subjects, and they were assured about confidentiality and anonymity of personal information, afterward, the written informed consent was obtained. We took an intravenous blood sample from each subject via the defined standard method [25]; the patients were made to lie down in a comfortable position, then, the tourniquet was tied up in 2-3 cm higher than elbow. The skin over the median cubital vein was disinfected by 70% alcohol. Almost 5 cc blood sample was taken via a syringe manufactured by Supa company, then after, 1 cc blood was poured into the citrate tube to determine the haemoglobin (Hb), and other for determining BG in laboratory. In the final step, the

blood samples were transferred to the laboratory within 30 minute. A lancet to insert to the tip of patients' finger, then, according to the Hortensius J et al., approach [20], the blood drops of the fingertips, were put upon the glucometers' strips (Beurer Bionime and Accu-chek). In a similar way, other blood samples were taken from the fourth fingertip. All of the BG measures were read and recorded in the provided information form.

STATISTICAL ANALYSIS

The data was entered into the SPSS-version 16.0 software. First, the true positive, true negative, false positive and false negative of the diagnostic value were determined. Thus, we calculated Positive Predictive Value (PPV), negative predictive value, sensitivity, specificity, accuracy, and precision. Paired t-test was applied to specify the precision and Kappa agreement coefficient to compare the agreement between the glucometers, its score is between -1 to 1, more score indicates more reliability. The sensitivity and specificity tests were used to determine accuracy. We also designed a ROC curve to demonstrate the sensitivity and specificity in order to show accuracy (the area under each ROC curve). The significant level of the tests was considered at 0.05.

RESULTS

Of the 257 patients, 122 (47%) were male, 141 (55%) diabetic and 184 (72%) married. The mean and Standard Deviation (SD) for age was 59.7 ± 16.08 years. Approximately, 79% of patients (202 individuals) had an education level less than diploma, and 59% (151 people) were unemployed. The fasting BG of 51% (131 people) was in range of normal (less than 115 mg/dl) and others were higher (more than 115).

According to the results of Pearson's correlation coefficient, there was a positive correlation between the three BG measurement methods compared to the standard, significantly, but this correlation was higher with the Beurer glucometer ($r=0.976$, $p<0.001$), then Bionime ($r=0.972$, $p<0.001$) and Accu-chek ($r=0.876$, $p<0.001$). However, in the repeated measurements of BG, two of the glucometers; Beurer ($t=0.96$, $p=0.92$), and Bionime ($t=0.50$, $p=0.61$), had no significant differences by paired t-test, but this difference was found for Accu-chek ($t=2.7$, $p=0.006$). This indicates an acceptable precision of Beurer and Bionime glucometers.

For determining accuracy, the sensitivity of Beurer glucometer was 96%, higher than Bionime (82%) and Accu-chek (81%). In this regard, the highest specificity was related to the Bionime (70%). The PPV of Beurer, and Bionime was 77% and Beurer had the most NPV (93%) [Table/Fig-1].

The agreement between Beurer and Bionime was calculated to be 82.2% (very good agreement), but this rate was 70.8% for Bionime and Accu-chek (a good agreement) [Table/Fig-2].

ROC curve indicates the overall sensitivity and specificity of the glucometer devices in comparison to the standard method, of which Beurer had the highest sensitivity and specificity with regard to the area under of ROC curve (0.911). Moreover, this rate for Bionime and Accu-chek was 0.853 and 0.835, respectively [Table/Fig-3].

DISCUSSION

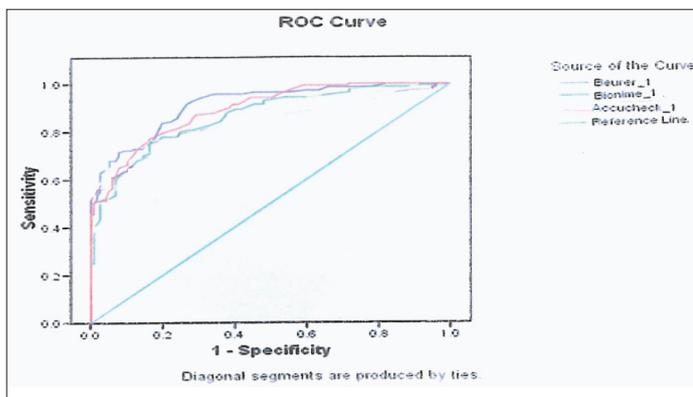
The results represented that Beurer glucometer has the most accuracy than Bionime and Accu-chek, and its sensitivity, specificity, PPV and NPV were 96%, 66%, 77% and 93%, respectively. In

Glucometer Index	Sensitivity	Specificity	PPV	NPV	Precision (paired t-test)	Kappa agreement	Accuracy
Beurer	96%	66%	77%	93%	0.96	82.2%	82%
Bionime	82%	70%	77%	75%	0.50	78%	76%
Accu-chek	81%	65%	74%	74%	2.7	70.8%	74%

[Table/Fig-1]: Accuracy, precision, sensitivity, specificity, PPV and NPV of the different glucometer measurements.

Glucometers Index	Kappa coefficient (%)	p-value
Beurer- Bionime	82.2	p<0.001
Beurer- Accu -chek	78	p<0.001
Bionime -Accu -chek	70.8	p<0.001

[Table/Fig-2]: The agreement between the glucometers to measure the BG.



[Table/Fig-3]: The area under curve by using the ROC curve.

accordance with our study, Freckmann G et al., tested the precision of 43 common glucometers in Europe. They concluded, Beurer glucometer has the most appropriate accuracy [26]. In a study by Girouard J et al., the accuracy of Beurer glucometer for assessing BG of 333 neonate infants were addressed, in which the findings verified a high correlation ($r=0.916$) between the glucometer and laboratory test, indicating a high accuracy [27].

The precision of the Beurer glucometer also was approved in our study {no significant difference in repeated measures of BG via paired t-test ($t=0.96$, $p=0.92$)}. We could not find any evidence regarding the precision of Beurer glucometer in the databases of PubMed, Science Direct and Google Scholar. However, with respect to our findings, it is suggested to use the Beurer glucometer for measuring the BG of diabetic patients at home and hospitals.

We found the accuracy of Bionime glucometer to be acceptable by its sensitivity of 82%, specificity 70%, PPV 77% and NPV 75%. Moreover, regarding non-significant difference by paired t-test, the precision also was possible. Accordingly, Wu MH et al., in a study on 143 diabetic patients, found Bionime glucometer to best correlate with the standard laboratory tests ($r=0.997$, $p<0.001$) [28]. In accordance with our study, other researchers also confirmed the accuracy and precision of the Bionime glucometer [13,29].

We found the Accu-chek glucometer to have an acceptable accuracy with the sensitivity of 81%, specificity 65%, PPV 74% and NPV 74%. Accordingly, in a similar study by Nooripoor S et al., the BG of the infants were evaluated. They demonstrated a plausible correlation between Accu-chek glucometer and the standard laboratory approach, which achieved an appropriate accuracy [30]. In a study by Aghakachoei S et al., the accuracy of Accu-chek and Clevercheck glucometers for the diabetic and non-diabetic clients had been investigated. The Accu-chek glucometer was more accurate than Clevercheck [31]. Nevertheless, contrary to our results, Critchell CD et al., reported the lack of accuracy by Accu-chek glucometer [24]. Moreover, in the current study the repeated measures of BG for Accu-chek glucometer were significantly different, which indicates a lack of precision. This is not in accordance with the study by Nooripoor et al., [30]. Regarding the lack of precision related to the Accu-chek glucometer, it is suggested to conduct more investigations to examine the accuracy and precision of this device.

LIMITATION

The BG level is affected by other factors such as patient status, examiner characteristics, and environmental conditions. We had taken some efforts in order to reduce such biases, for example, the

interventions were done in a similar condition, as well as a skillful co-worker performed all the examinations. However, few confounders might have retained.

This study served to assess the accuracy and precision of only three common glucometers in the internal units, hence, it is suggested further inquiries and trials are required in other units too.

CONCLUSION

Given the results of this study, the Beurer glucometer had the highest accuracy and precision for measuring the BG of diabetic patients. The Bionime glucometer indicated an acceptable accuracy and precision. So it is suggested to apply the Beurer and Bionime glucometers for diabetic patients at home and the hospitals. However, the Accu-chek glucometer needs more studies to determine its accuracy.

AUTHORS CONTRIBUTION

All the authors contributed to the process of the study. The conception of the study was conducted by SKK, AK and RJ. SKK and AK wrote the project design, the data was gathered by SKK and analyzed by MR, and then the article was written by SKK, AK and AA. All the authors confirmed the final draft of the paper.

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