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Accuracy of Sensocard Glucose Meter: Comparing with Reference Glucose Oxidase Method

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Abstract

Introduction: Diabetes mellitus is a cause of morbidity, disability and mortality worldwide. Glucose measurement by glucose meter is one of the diagnosing and monitoring tools of diabetes mellitus. However, the accuracy of this instrument is in question. Therefore, the aim of this study was to assess the accuracy of SensoCard glucose meter comparing with reference glucose oxidase method at University of Gondar Hospital, Gondar, Ethiopia.

Methods: A prospective cross-sectional study was conducted in March, 2014. A total of 122 (equal number of type 1 and II) diabetic mellitus patients were selected by consecutive sampling technique. Glucose value was determined by SensoCard glucose meter and reference glucose oxidase method. The data were entered and analyzed using SPSS version 20 and Analyse-it version 3.76.1 softwares. Correlation coefficient and bias were calculated to observe the agreement of the glucose meter result with the comparative method. The minimum accuracy of Sensocard was determined based ISO 15197:2003 and ISO 15197:2013 criteria.

Results: Sixty three (51.6%) participants were females. The mean age was 46.16 ± 15.5. The mean serum glucose value measured by reference method was 164.78 ± 86.33 mg/dl and the mean capillary blood glucose value measured by SensoCard glucose meter was 161.19 ± 78.1 mg/dl. There was no statistically significant difference between the means of SensoCard glucose meter and reference method glucose value (p-value=0.052). The correlation coefficient between the two methods was 0.975. The SensoCard glucose meter underestimated the overall glucose value from the reference method glucose value by a bias of 3.59.

Conclusion: SensoCard did not fulfill the minimum accuracy requirements of ISO 15197:2003 and ISO 15197:2013. Further study should be undertaken including hypoglycemic and normoglycemic individuals to see the accuracy of SensoCard in low and normal levels of blood glucose in addition to high blood glucose level in diabetes mellitus patients.

Keywords: Accuracy; Bias; Diabetes mellitus; Glucose oxidase; SensoCard

Abbreviations: 4-AAP: 4 Amino-antipyrene; BG: Blood glucose; CI: Confidence interval; DM: Diabetes mellitus; FAD: Flavin adenine dinucleotide; Fc: Ferrocenecarboxylate; GOD: Glucose oxidase; ISO: International organization for standardization; MDI: Multiple-dose insulin; POC: Point-of-care; POD: Peroxidase; SD: Standard deviation; SMBG: Self-monitoring of blood glucose

Introduction

Diabetes mellitus (DM) is a chronic disease which requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of long-term complications. Diabetes care is complex and needs multifactorial risk reduction strategies in addition to glycemic control [1]. Management of blood glucose (BG) in an acceptable range is a major therapy target for diabetes patients in both the hospital and outpatient settings [2]. Patients on Multiple-dose Insulin (MDI) or insulin pump therapy should do self-monitoring of blood glucose (SMBG) at least prior to meals and snacks, occasionally postprandially, prior to exercise, at bedtime, when they suspect low blood glucose, after treating low blood glucose and prior to critical tasks such as driving [1]. Self-monitoring blood glucose systems have the potential to play an important role in the control of diabetes and in the reduction of risk of serious secondary clinical complications [3]. The advantages of these Point-of-Care (POC) testing are reduced therapeutic turnaround time of diagnostic testing, reduced preanalytic and postanalytic testing errors, rapid data availability, self-contained and user-friendly instruments, shorter patient length of stay, small sample volume for a large test menu, convenience for clinicians and ability to test many types of samples [4].

Various POC tests have been found to be non-inferior to laboratory testing for managing chronic conditions in general practice and aboriginal medical services. Maintaining the diagnostic quality of devices and ensuring that staffs are properly trained are critical elements in sustaining a high quality POC testing service [5]. The accuracy of the POC glucose monitor depends on device methodology and other factors, like sample source and collection and patient characteristics. Human parameters capable of influencing measurements include variations in pH, hematocrit, blood oxygen, changes in vasopressor and microcirculation therapy. These elements alone or when combined can significantly impact BG measurement accuracy with POC glucose monitoring devices [2]. Since inaccurate systems bear the risk of false therapeutic decisions, standardized and regular evaluation of BG meters and test strips should be requested in order to ensure adherence

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to accuracy and quality standards [6]. The use of glucose meters like SensoCard for blood glucose monitoring in DM patients is increasing from time to time in Ethiopia. Therefore, the aim of this study was to assess the accuracy of SensoCard glucose meter comparing with reference glucose oxidase method at University of Gondar Hospital, Gondar, Ethiopia.

The SensoCard blood glucose meter is the size of a credit card and is easy to operate. It uses advanced biosensor technology to measure glucose levels in the tiniest drop of blood, in average of 5 seconds. The electrochemical method uses glucose oxidase (GOD) enzymes which specifically catalyzes glucose and reduce interferences. This makes it an improved specific method of determination of blood glucose than other glucose meters which did not follow this principle. Its measuring range is 20-600 mg/dl concentration of glucose. It works in an optimum temperature of 10-40°C. The meter stores the last 500 results in its memory. It is much better and cheaper than anything people could get hold [7-9].

Materials and Methods

Study design, setting and period

A prospective cross-sectional study was conducted in March, 2014 at University of Gondar Hospital. Diabetic mellitus patients who have come to the hospital for follow up were participated in the study. Equal number of type I and type II DM patients were selected by consecutive sampling technique. Diabetes mellitus patients who were volunteers, who have normal hematocrit value and who were not on medication that affects glucometer measurement like acetaminophen and vitamin C were included in the study.

Data collection

After having received a clear clarification of the aim, risk and confidentiality of the study, participants have signed the informed consent and participated in the study. One hundred twenty two (61 type I and 61 type II DM) participants were enrolled. Demographic information including sex, age and type of DM were collected using data abstracting sheet. Blood samples were collected from the ante cubital vein and capillary of finger for the reference glucose oxidase method and SensoCard glucose meter glucose measurement, respectively after an overnight fasting (12-16 h). Tourniquet was applied for less than one minute, for vein puncture and the sites of blood collection were cleaned by 70% alcohol. The venous blood sample was taken to the laboratory and centrifuged at 500 g for 5 minutes to obtain the serum. All measurements were done according to the manufacturer's instructions. Capillary blood glucose was determined by SensoCard glucose meter (77 Elektronika Kft., Budapest, Hungary) and venous blood glucose was measured by BioSystems A25 Chemistry Analyzer (BioSystems S.A, Spain) using glucose oxidase test method. Duplicate measurement of blood glucose was performed by each instrument and the average of each was taken as single glucose value.

Principle of glucose oxidase method: Glucose level was determined by an enzymatic spectrophotometric glucose oxidase method. The basic principle is that, Glucose is oxidized by glucose oxidase (GOD) enzyme to produce gluconate and hydrogen peroxide (H_2O_2). The H_2O_2 is then oxidatively coupled with 4 amino-antipyrene (4-AAP) and phenol in the presence of peroxidase (POD) enzyme to yield a red quinoeimine dye that is measured at 505 nm with a spectrophotometer (BioSystems A25 Chemistry analyzer). The absorbance at 505 nm is proportional to concentration of glucose in the sample. The method has linearity from 0.0126 mmol/l (0.23 mg/dl) to 27.5 mmol/l (500 mg/dl).

$$\text{Glucose} + 2H_2O + O_2 \xrightarrow{\text{GOD}} \text{Gluconate} + H_2O_2$$

$$2H_2O_2 + \text{4-AAP} + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinoeimine Dye} + 4H_2O$$

Absorbance of the colored solution is directly proportional to the glucose concentration when measured at 505 nm [8].

Principle of the SensoCard: The Sensocard analysis applies the enzyme glucose oxidase and is based on advanced electrochemical technology that is specific for β-D-glucose measurement. Test strips are designed in such a way that the blood sample absorbs into the reaction area, after blood sample has been applied to the tip of test strip. In the reagent zone, glucose oxidase initiates the oxidation of glucose in blood. Intensity of produced electrons is measured by the meter and correlates well with the concentration of glucose in the blood sample. According to the manufacturer manual, the test is linear up to 33.3 mmol/l (600 mg/dl). This method will accurately measure glucose levels down to 1.1 mmol/l (20 mg/dl) [9].

The Sensocard sensor is constructed on electrodes and uses GOD enzyme and ferrocenecarboxylate (Fc) mediator to carry electrons from GOD to electrode. Flavin adenine dinucleotide (FAD) is used as a coenzyme during the enzymatic reaction. The produced current under the applied electric voltage is measured by amperometr and then converted to glucose concentration. The intensity of formed electrons is directly proportional to glucose concentration [9].

$$\text{Glucose} + \text{GOD(FAD)} + 2H^+ \rightarrow \text{Gluconolactone} + \text{GOD}(FADH_2)$$

$$\text{GOD}(FADH_2) + 2Fc^+ \rightarrow \text{GOD(FAD)} + 2Fc + 2H^+$$

$$Fc \rightarrow Fc^+ + 2e^- \text{ (at electrode)}$$

Accuracy evaluation

Accuracy of SensoCard glucose meter for fingertip capillary blood testing was assessed at University of Gondar Hospital. At the study site, we tested the participants' fingertip blood glucose with the SensoCard and ante cubital vein blood glucose with BioSystems A25 Chemistry Analyzer spectrophotometer, which served as the reference. Accuracy was evaluated using International Organization for Standardization (ISO) 15197:2003 and ISO 15197:2013 requirements by calculating the percentage of meter results falling within ±5%, ±10%, ±15% and ±20% of the reference value for glucose concentrations ≥75 mg/dl and ≥100 mg/dl and within ±5, ±10, ±15 and ±20 mg/dl of the reference value for glucose concentrations <75 mg/dl and <100 mg/dl. The minimum acceptable accuracy for results produced by SensoCard glucose meter according to ISO 15197:2003, is: ≥95% of the individual glucose results shall fall within ±15 mg/dl of the results of the manufacturer's measurement procedure at glucose concentrations <75 mg/dl and within ±20% at glucose concentrations ≥75 mg/dl and according to ISO 15197:2013, is: ≥95% of the individual glucose results shall fall within ±15 mg/dl of the results of the manufacturer's measurement procedure at glucose concentrations <100 mg/dl and within ±15% at glucose concentrations ≥100 mg/dl [10,11]. In addition, the Bland–Altman plot was used to estimate the difference (bias) limits containing 95% of data because normally distributed differences were needed [12].

Data analysis

The data were entered and analyzed using Statistical Package for Social Sciences (SPSS) version 20 (IBM Statistics, USA) and Analyse-it version 3.76.1 (Analyse-it Software, Ltd., UK) softwares. The Bland-Altman analysis was used to see the agreement of SensoCard glucose meter with reference spectrophotometric glucose oxidase method in measuring blood glucose concentration. Correlation coefficient and

regression line were used to observe the degree of association of the Sensocard with the reference method. T-test was also used to compare the glucose concentration among varies groups and categories of participants. P-Value <0.05 was considered to be statistically significant at 95% confidence interval (CI).

Ethical consideration

The study was ethically cleared from the Research and Ethical Committee of School of Biomedical and Laboratory Sciences, College of Medicine and Health Sciences, University of Gondar. Data were collected after written consent was obtained from the study participants. To keep confidentiality, non-identifier codes were used and unauthorized person could not able to access the data.

Results

A total of 122 DM patients were included in this study. Of these, 51.6% (n=63) were females. The mean age was 46.16 ± 15.5 (range 17-77) years. Half (50%) of the study participants were type 1 DM and the other half were type II DM patients. The mean serum glucose value measured by reference glucose oxidase method was 164.78 ± 86.33 mg/dl (range 42-533) and the mean capillary blood glucose value measured by SensoCard glucose meter was 161.19 ± 78.1 mg/dl (range 65-491). There was no statistically significant difference between the means of SensoCard glucose meter and reference glucose oxidase method glucose value (p-value=0.052). The bias of SensoCard was 3.59 and the strength of association (correlation coefficient) between the two methods was 0.975 (Table 1).

The mean difference (bias) between the two methods was not associated with sex, age and DM type. However, the mean bias showed statistically significant association with glucose value. The mean bias increases as glucose value increase in both methods (p-value <0.0001 and 0.016 for glucose oxidase method and SensoCard method, respectively) (Table 2).

The slope of the regression line for reference glucose oxidase method versus SensoCard glucose meter glucose values was 0.8817 with a positive intercept of 15.9 mg/dl. Under simultaneous equation the Y=X and Y=0.8817x+15.9 graphs meet at 134 mg/dl glucose concentration. According to the equation, the SensoCard glucose meter overestimated the glucose concentrations below 134 mg/dl and underestimated glucose concentrations above 134 mg/dl (Figure 1).

The Bland-Altman plot showed that most of the difference (bias) glucose values between SensoCard glucose meter and reference glucose oxidase methods lay within the bias ±1.96SD (95% CI). The 95% limit of agreement was -35.93 to 43.11 (Figure 2).

The percentage of SensoCard blood glucose values within different deviation ranges of glucose oxidase reference method is shown below.

Parameters		SensoCard method	Glucose oxidase method
Minimum		65	42
Percentiles	25	109.875	109.5
	50	139.5	141.5
	75	177.375	196.25
Maximum		491	533
Mean		161.19	164.78
Standard deviation		78.08	86.33
Coefficient of variation (%)		48.44	52.39
Difference between means (bias) P-value 95% confidence interval Correlation coefficient		3.59 0.052 -0.02387 to 7.2042 0.975	

Table 1: General characteristics of the two methods' glucose value of patents at University of Gondar Hospital, Gondar, Ethiopia, 2014.

Variables		Number (N=122)	Mean Bias	SD of bias	P-value	CI
Gender	Male	59	1.4492	20.47616	0.258	-11.37, 3.08
	Female	63	5.5952	19.81830		
Type of DM	Type 1	61	4.8689	20.30454	0.486	-4.69, 9.8
	Type2	61	2.3115	20.10683		
Age (year)	≤48	61	6.3443	20.17415	0.132	-1.68,12.7
	> 48	61	0.8361	19.93651		
Glucose oxidase glucose value	≤134 mg/dl	54	-7.0556	11.73877	<0.0001	-25.54, -12.66
	>134 mg/dl	68	12.0441	21.47886		
SensoCard glucose value	≤134 mg/dl	56	-1.1696	15.2903	0.016	-15.91, -1.69
	>134 mg/dl	66	7.6288	22.86723		

Table 2: Association between mean bias of glucose value of SensoCard with other variables among DM patients at University of Gondar Hospital, Gondar, Ethiopia, 2014.

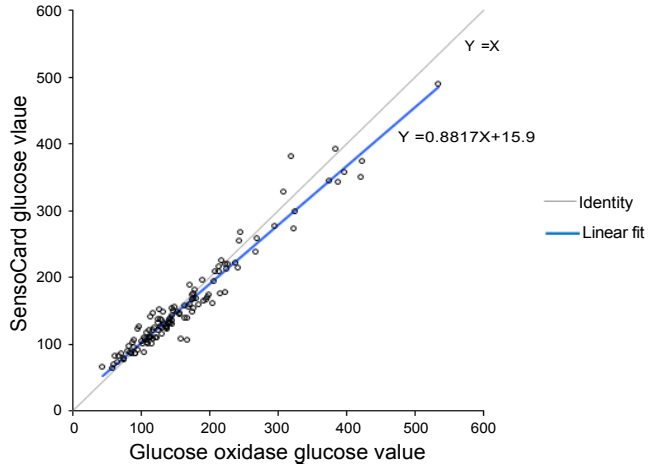

Figure 1: Linear regression graph of reference glucose oxidase glucose value versus SensoCard glucose meter glucose value of DM patients at University of Gondar Hospital, Gondar, Ethiopia, 2014.

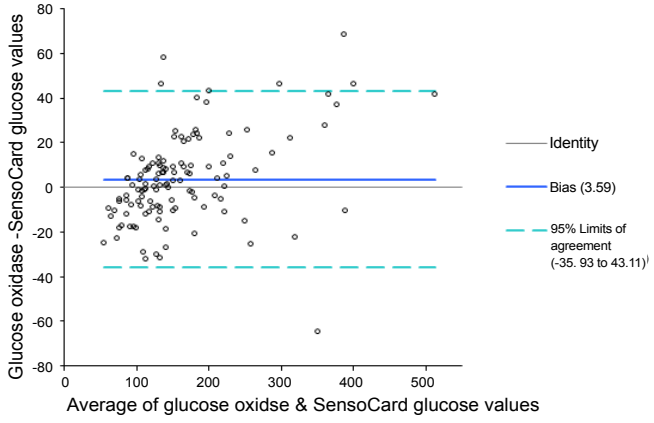

Figure 2: The bias plot (Bland-Altman plot) of DM patients' glucose value between SensoCard glucose meter and reference glucose oxidase methods at University of Gondar Hospital, Gondar, Ethiopia, 2014.

Cut point of the reference method	Percentage of SensoCard glucose levels within the reference method intervals				
	Within ± 5%(5 mg/dl)	Within ± 10%(10 mg/dl)	Within ± 15%(15 mg/dl)	Within ± 20%(20 mg/dl)	Beyond ± 20%(20 mg/dl)
<75 mg/dl	1/9(11.1%)	3/9(33.3%)	5/9(55.6%)	7/9(77.8%)	2/9(22.2%)
≥75 mg/dl	40/113(35.4%)	77/113(68.1%)	97/113(85.8%)	102/113(90.3%)	11/113(9.7%)
Over all	41/122(33.6%)	80/122(65.6%)	102/122(83.6)	109/122(89.3%)	13/122(10.7%)
< 100 mg/dl	5/22 (22.7%)	10/22(45.5%)	13/22(59.1%)	18/22(81.8%)	4/22(18.2%)
≥100 mg/dl	34/100(34%)	69/100(69%)	86/100(86%)	84/100(94%)	6/100(6%)
Over all	39/122(32%)	79/122(64.8%)	99/122 (81.1%)	112/122(91.8%)	10/122(8.2%)

For glucose concentrations <75 and <100 mg/dl, the % meter results within ± the specified mg/dl of the reference glucose values are tabulated. For glucose concentrations ≥75 and ≥100 mg/dl, the % meter results within ± the specified % of the reference glucose values are tabulated.

Table 3: Percentage of SensoCard glucose meter results falling within various intervals of the reference glucose oxidase glucose value of DM patients at University of Gondar Hospital, Gondar, Ethiopia, 2014.

According to ISO 15197 standards, SensoCard results within ±20, ±15, ±10, and ±5 mg/dl of the reference results at blood glucose concentrations <75 and <100 mg/dl and SensoCard results within ±20%, ±15%, ±10%, and ±5% of the reference results at blood glucose concentrations ≥75 and ≥100 mg/dl are calculated (Table 3).

Discussion

In this study, the minimum and maximum glucose concentration measured by SensoCard glucose meter and reference glucose oxidase methods were 65 mg/dl and 491 mg/dl and, 42 mg/dl and 533 mg/dl, respectively. The mean capillary blood glucose value measured by SensoCard glucose meter was 161.19 ± 78.1 mg/dl and the mean serum glucose value measured by reference glucose oxidase method was 164.78 ± 86.33 mg/dl and. There was no statistically significant difference between the means of SensoCard glucose meter and reference glucose oxidase method glucose value (p-value=0.052) (Table 1) but the p trend approaches 0.05 and a bigger sample may yield statistically different results. Although the discrepancy between SensoCard and reference glucose oxidase glucose values were not statistically significant from this study, the magnitude of these differences could be considered clinically significant if the glucose values could change treatment decisions in a situation requiring precise glucose measurements.

The mean difference (bias) between the two methods was 3.59. The mean bias was not associated with gender, DM type and age (p-value=0.258, 0.486 and 0.132, respectively). However, the mean bias showed statistically significant association with both reference glucose oxidase method and SensoCard glucose values (p-value <0.001 and 0.016, respectively) (Table 2). The bias between the two methods increases as the concentration of glucose increases. Compared to the reference glucose oxidase method, the SensoCard glucose meter has over estimated and under estimated glucose concentrations in lower and higher concentrations of glucose, respectively. This may be due to the accuracy problem of the SensoCard glucose meter method to determine the lower and especially the higher glucose concentrations.

From the Bland-Altman analysis in Figure 2, when the reference glucose oxidase method was compared to the SensoCard glucose meter, it indicated that the SensoCard was generating glucose results lower than that of the reference method. This is in line with the above observation in Table 1. The bias from this was 3.59 and the 95% limit of agreement was -35.93 to 43.11 (Figure 2). Similarly, another study comparing SensoCard with reference glucose oxidase method found a bias of 3.6 and the 95% limit of agreement was -30 to 37.8 [13].

This study showed that, 55.6% and 90.3% of the SensoCard glucose measurement results fall within ±15 mg/dl and ±20% of the results of the reference glucose oxidase method at glucose concentrations <75 mg/dl and ≥75 mg/dl, respectively. In addition, 59.1% and 86% of the SensoCard glucose measurement results fall within ±15 mg/dl and ±15% of the results of the reference glucose oxidase method at glucose concentrations <100 mg/dl and ≥100 mg/dl, respectively. However, according to ISO 15197 criteria ≥95% the SensoCard glucose measurement results should fall within the above reference glucose value intervals [10,11]. Therefore, SensoCard glucose meter did not fulfill the minimum accuracy requirements of ISO 15197. In spite of our SensoCard result, a study done in other place fulfilled the ISO 15197 criteria. In this study, 97% and 99% of the SensoCard glucose measurement results fall within ±15 mg/dl and ±20% of the results of the reference glucose oxidase method at glucose concentrations <75 mg/dl ≥75 mg/dl, respectively [14].

Limitations of the study

The study was done only on DM patients (majorly hyperglycemic level) and it was not possible to see the accuracy of SensoCard glucose meter at lower glucose (hypoglycemic and normoglycemic) levels.

Conclusion

The SensoCard glucose meter and the reference glucose oxidase methods showed a good correlation of 0.975 in determining blood glucose concentrations. In addition, there was no statistically significant difference between the means of blood glucose values between the two methods. However, SensoCard glucose meter underestimate blood glucose value averagely by 3.59 from reference glucose oxidase method. Moreover, the SensoCard glucose meter did not fulfill the minimum accuracy requirements of ISO 15197:2003 and ISO 15197:2013. Further study should be undertaken including hypoglycemic and normoglycemic individuals to see the accuracy of SensoCard in low and normal levels of blood glucose in addition to high blood glucose level in diabetes mellitus patients.

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