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Original Article

Evaluation of the accuracy and precision of glucometers currently used in Sri Lanka



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ABSTRACT

Aims: Life threatening macrovascular and microvascular complications of diabetes can be minimized by effective glycaemic control. Self monitoring of blood glucose with glucometers is recognized as a cost effective strategy to improve glycaemic control. However accuracy and precision of glucometers will determine the effectiveness of this strategy. We aimed to evaluate accuracy and precision of commonly used glucometers in Sri Lanka.

Materials and methods: An observational study was conducted in a tertiary care setting including patients with diabetes and healthy volunteers. Eight commonly used glucometers were used. Blood glucose was measured in 50 participants (16 healthy volunteers, 34 patients with diabetes) in finger prick capillary blood using glucometers and venous blood using standard laboratory methods, and were compared to determine accuracy. Repeated measurements from same glucometer with a single finger prick were made and compared to determine precision.

Results: Only one glucometer showed insignificant difference to venous plasma glucose values. Only one glucometer met ADA recommended bias of <5%. None of the glucometers fell within the ISO recommendations for accuracy.

Conclusion: Majority of commonly used glucometers in Sri Lanka do not meet the ADA recommendations and ISO standards for accuracy and precision. However their variations are unlikely to make significant adverse impact on patient management.

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1. Background

Diabetes Mellitus is a metabolic disorder characterized by

chronic hyperglycaemia due to defects in insulin secretion, action or both. It is a global epidemic and the prevalence is increasing in developing world than in developed world. Extent of this problem in Sri Lanka is reflected in its high overall prevalence figure of 10.3% in adults with 16.4% prevalence in urban population. 21.8% of total population has some form of dysglycaemia [1].

Diabetes is associated with life threatening macrovascular and microvascular complications [2]. However incidence of such complications can be minimized by good glycaemic control [3–5]. Optimum glycaemic control depends on pharmacological and lifestyle measures as well as regular monitoring.

Self Monitoring of Blood Glucose (SMBG) is recognized as a major component of effective management of diabetes. American Diabetes Association (ADA) recommends it for all insulin-treated

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patients. Benefits of SMBG include achieving and maintaining glycaemic control, preventing and detecting hypoglycaemia, avoiding severe hyperglycemia, adjusting care in response to changes in lifestyle, and establishing the need for initiating insulin therapy in gestational diabetes mellitus. Patients with type 1 diabetes mellitus and pregnant women who are on insulin are recommended to have three or more SMBG daily. The optimal frequency and timing of SMBG for patients with type 2 diabetes is unknown but should be sufficient enough to achieve optimal glycaemic control [6].

However, effectiveness of SMBG depends on accuracy of glucometers. Advancing technology has generated a competition among glucometer producers to improve accuracy and reliability of glucometers [7], despite these technical advances, variations among glucometers continue to exist, necessitating the implementation of glucometer guidelines and standards by both ADA and International Organization for Standardization (ISO). The ADA recommends an analytical error of $\leq 5\%$ across all levels [8] and according to ISO for test readings >4.2 mmol/L (75 mg/dL), the discrepancy between meters and an accredited laboratory should be $<20\%$; for glucose readings ≤ 4.2 mmol/L (75 mg/dL), the discrepancy should not exceed 0.83 mmol/L (15 mg/dL) in 95% of the samples [9].

Studies on glucometer accuracies from Sri Lanka as well as from the South Asian region are limited. It is therefore important to compare both the accuracy and precision of currently available glucometers in Sri Lanka. The aim of this study was to assess the accuracy and precision of commonly available glucometers in Sri Lanka and to establish whether they fall within the recommended standards of the ADA and ISO.

2. Methods

This was a cross sectional study which was conducted in 2012–13 in two phases. The first phase took place at the Diabetes Research Unit and the second phase at the National Hospital of Sri Lanka. In the first phase precision of the glucometers was determined using both the high and low concentration control solutions. In the second phase capillary whole blood glucometer readings were compared with the laboratory reference method.

To assess the precision, glucose concentration was checked 20 times with each glucometer using their respective reference high and low concentration solutions using six glucometers (reference glucose solutions for glucometer E and G were not available in the country). Mean, Standard Deviation (SD) and Coefficient of Variation (CV) for each device at high and low glucose levels were calculated.

50 participants were recruited by convenient sampling method, to include 16 healthy volunteers and 34 patients with diabetes admitted to University Medical Unit of National Hospital of Sri Lanka. Eight latest and commonly used portable glucometers were identified and a venous sample (VS) from each individual was taken into a sodium fluoride/potassium oxalate tube and was analysed for glucose using glucose oxidase peroxidase method (Trinder's

method) in a standardized laboratory. Simultaneously capillary blood was obtained using a sterile lancet fixed in a spring-loaded device, by a single finger prick and was applied directly from the fingertip to all the reagent strips and finger prick (FP) values also were determined using all glucometers. Each glucometer was calibrated to plasma prior to use. All samples were collected and tested by a trained pre intern doctor in order to limit operator variability.

To compare the accuracy of each meter to the reference method, several analyses were undertaken. Paired *t*-test for each glucometer was done with the reference biochemical method, The Bland-Altman plot was used to compare the glucometer values with the venous value and the Clarke error grid analysis was performed to determine the clinical significance of the differences between the meter and reference value. The ISO-allowable analytical error was also graphed in these plots. Bias was also calculated for each meter, as the mean of the difference between the reference and test meter as a percentage of the reference value and accuracy was assessed by ADA and ISO guidelines. All the glucometers in this study were calibrated to plasma. SPSS 17 was used for the statistical analysis.

3. Results

The coefficients of variation (CV) of the glucometers were calculated using the high and low concentration control solutions and are shown in Table 1. The coefficients of variation ranged from 1.86% to 15.58% for the low concentration control solution, and 0.92% to 19.21% for the high concentration control solution.

In the second phase of the study, venous plasma glucose levels were distributed between 59 and 448 mg/dL. Mean difference between VS and FP values were determined and 95% confidence intervals and *P* values were calculated for all the glucometers (Table 2). Apart from Glucometer 'F' all the other glucometers showed a statistically significant difference between VS and FP values.

Bias was assessed using ADA guidelines, and Table 3 shows the bias values for all the glucometers. Most of them showed a negative bias. Only glucometer 'C' showed a positive bias. 'F' and 'C'

Table 2
Comparison of venous plasma glucose and capillary glucose measurements using different glucometers.

Glucometer	Mean difference between VPG and FPG values	95% confidence interval		<i>P</i>
A	-6.96	-11.66	-2.25	0.005
B	-17.42	-23.78	-11.05	<0.001
C	7.92	+1.43	+14.40	0.018
D	-13.84	-18.51	-9.16	<0.001
E	-10.2	-17.19	-3.20	0.005
F	1.78	-6.48	+10.04	0.667
G	-18.16	-25.07	-11.24	<0.001
H	-13.66	-20.40	-9.91	<0.001

VPS: venous plasma glucose, FPG: Finger prick glucose.

Table 1
Coefficient of variance of glucometers with high and low concentration glucose solutions.

Glucometer	CV % (low control)	CV % (high control)	SD (low control)	SD (high control)	Mean with low control (mg/dL)	Mean with high control (mg/dL)
A	1.86	0.92	0.85	2.74	45.90	298.50
B	15.36	19.20	7.33	45.72	47.75	235.00
C	8.26	1.89	3.12	6.22	37.80	337.85
D	15.58	5.97	9.24	17.62	59.30	300.55
F	4.24	4.61	6.35	14.54	149.55	315.30
H	8.02	14.92	4.42	33.74	55.10	226.10

CV: Coefficient of variance SD: standard deviation.

Table 3
Bias and ISO concordance of glucometers A – H.

Glucometer	Mean of the difference	Bias%	ISO concordance (%)
A	-6.96	-8.019	62
B	-17.42	-18.52	44
C	7.92	3.35	76
D	-13.84	-13.486	68
E	-10.2	-9.081	84
F	1.78	-0.977	72
G	-18.16	-13.776	50
H	-13.66	-14.130	70

ISO: International Organization of Standardization.

glucometers met the ADA recommendation of 5% bias getting -0.98% and 3.35% respectively.

The extent to which the glucometers deviated from the reference method is represented in Bland-Altman plots, as shown in Fig. 1. Table 3 shows the summary of the results of Bland – Altman plot. According to these values none of the glucometers manage to achieve the ISO recommendation but highest concordance was seen in glucometer “E” with 84% of its glucometer readings being within the ISO recommendations and lowest in glucometer “B” with only 44% reading falling within the ISO recommendations.

The Clarke error grid analysis indicated adequate clinical

accuracy of the glucometers with all measurements except for 1 lying in zones A and B, as seen in Fig. 2, indicating acceptable clinical accuracy of readings despite having sub optimal precision and accuracy.

4. Discussion

Self-monitoring of blood glucose at home with a glucometer is an important strategy to improve glycaemic control in people with diabetes. This requires a reliable device that can measure glycaemic level with reasonable accuracy and precision to detect both hypoglycaemia and hyperglycaemia. Much technological advances have been achieved in the recent past in enhancing accuracy, precision, portability and memory of these devices. Yet, concerns continue to prevail regarding the accuracy of commonly used glucometers at least in developing countries. To address these issues, both ADA and ISO have recommended certain guidelines regarding accuracy of glucometers.

In our study only glucometer “A” and “F” manage to achieve <5% coefficient of variation for the low concentration control solution, and “A”, “C” and “F” for the high concentration control solution.

A statistically significant differences between VS and FP values were noted in all glucometers except for the glucometer “F”. Despite technological advances aiming improvement of both

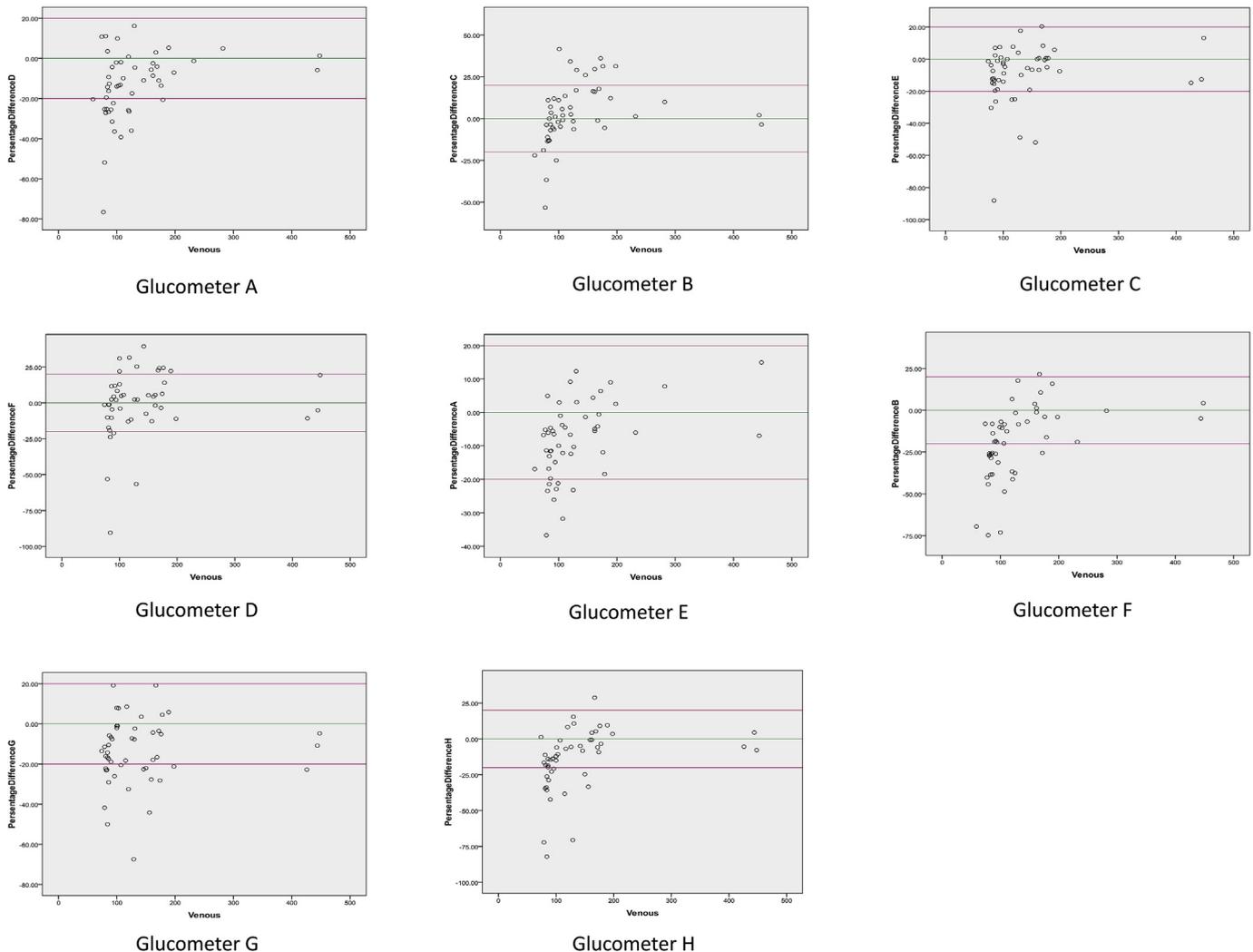


Fig. 1. Bland-Altman plot for glucometers A-H. Percentage difference of the glucometer measurement from the venous measurement plotted against venous blood glucose value.

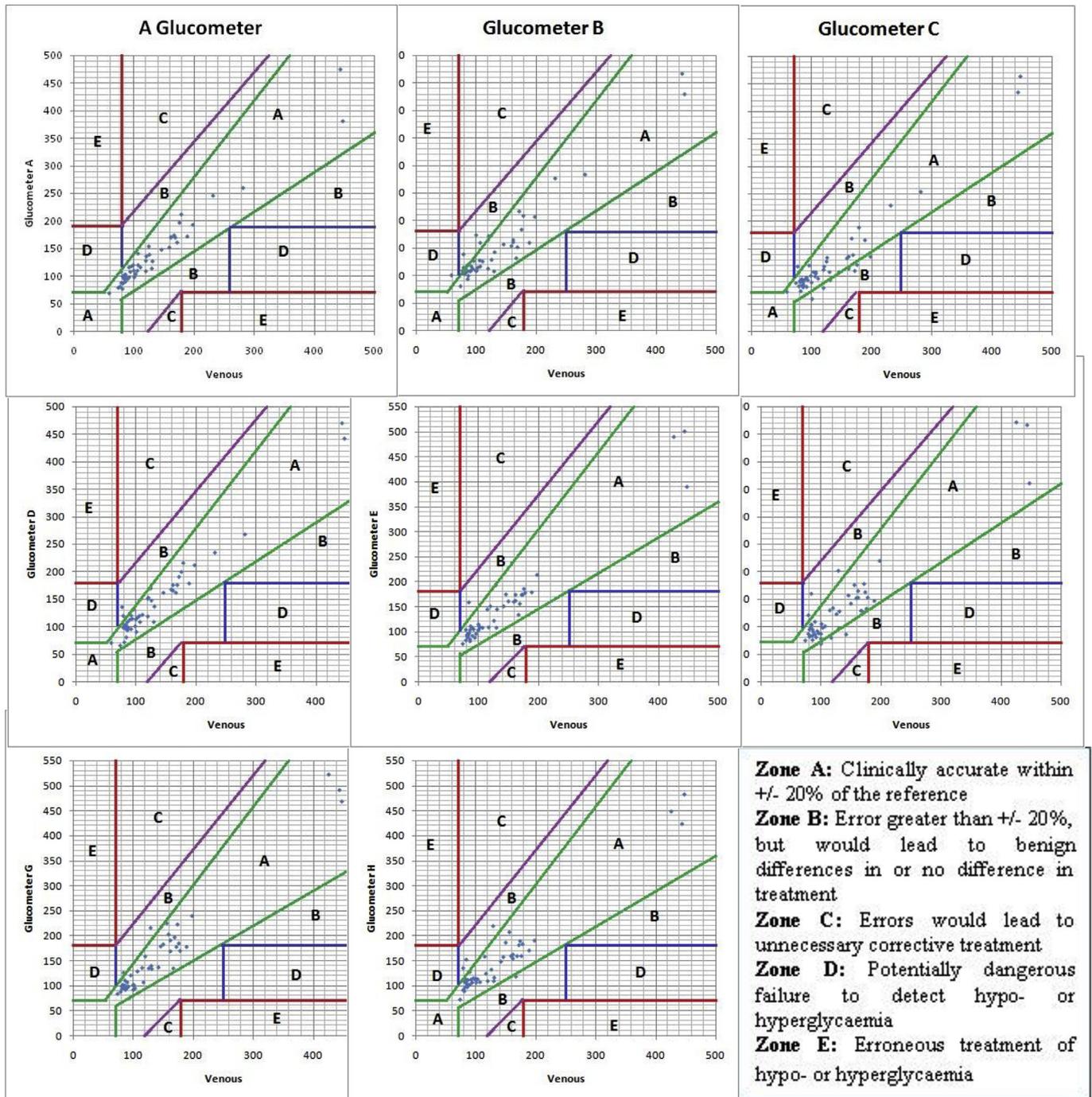


Fig. 2. Clarke error grid analysis for clinically significant accuracy of glucoimeters A–H.

precision and accuracy of glucoimeters only glucoimeter “F” and “C” met the ADA recommendation of <5% bias.

None of the glucoimeters managed to achieve the ISO recommendation but highest concordance was seen in glucoimeter “E” with 84% being inside the ISO recommendations and lowest in glucoimeter “B” 44% being inside the ISO recommendations.

However, studies from some other countries have yielded more encouraging results. In an Australian study where 5 glucoimeters were assessed all except one glucoimeter managed to get a <5% coefficient variation in both high and low concentration control solutions and all glucoimeters achieved ISO standard although only

one managed to achieve ADA recommendation of 5% bias [10]. According to Clarke Error Grid analysis results, all the glucoimeters showed adequate clinical accuracy with all measurements from all meters lying in zones A or B. All 3 glucoimeters that were tested in the study in New Zealand managed to achieve <5% coefficient variation in both high and low concentration control solutions, fulfilled the ISO recommendation and was clinically accurate according to Clarke Error grid analysis [11]. In South African study only three out of the five glucoimeters fulfilled the ISO guidelines but none manage to achieve ADA guideline. But all were clinically accurate according to Clarke error grid analysis [12].

The differences observed with glucometer value and the venous value can impact on patient care. Frequent insulin adjustments are made according to glucometer readings. Inaccuracies can lead to misclassification of hypo- or hyperglycaemic episodes. SMBG plays an important role in clinical intervention and in the monitoring process of diabetic patients. It is therefore important that glucometer values are accurate and precise. A failure in this may lead to critical medical errors. But in our study most of the glucometers showed adequate clinical accuracy according to Clarke error grid analysis. Most of the glucometer values fell predominantly in zone 'A', indicating a deviation of 20% or less from the reference value. Very few glucometer values fell in to zone 'B', signifying no or only benign change of treatment. Only one glucometer value fell in zone 'D', and none of the glucometer values fell in to Zones 'C' or 'E'. But there were only limited glucometer values from the hypoglycaemic range, as well as from the severe hyperglycaemic range. The glucometers used in this study showed adequate clinical accuracy but precision was not satisfactory as most of the glucometers showed a coefficient of variation of >5%.

5. Conclusions

Majority of commonly used glucometers in Sri Lanka do not meet the ADA recommendations and ISO standards for accuracy and precision. However, their variations are unlikely to make significant adverse impact on patient management. This study highlights the importance of an objective and independent rigorous quality assurances and post marketing surveillance of glucometers with time to time at both high and low concentrations of all glucometers available in the country. It also highlights that the patients should be properly advised when buying a glucometer and also to compare the accuracy with a venous sample intermittently.

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Abbreviations

ADA	American Diabetes Association
CV	Coefficient of Variance
FP	Finger prick
ISO	International Organization for Standardization
SD	Standard Deviation
SMBG	Self-Monitoring of Blood Glucose
VS	Venous sample

Ethics approval and consent to participate

All participants gave informed written consent for participation and dissemination of data. Ethical approval was obtained from Ethics Review Committee of National Hospital of Sri Lanka.

Consent for publication

Participants provided consent for publication of data maintaining anonymity.

Availability of data and material

Data set is available for reference with the first author and could be provided on written request.

Conflicts of interest

Authors have no conflicts of interest to declare.

Competing interests

Authors have no competing interests to declare.

Funding

None.

Authors' contributions

PK and GWK developed the research question and design. WAW, WMUAW, SS, TAD developed the research protocol. JHL, HAD, KKKG, GSPK, IRHSI conducted data collection and data entry. JHL, HAD, PNW analysed the data. JHL, HAD, KKKG, GSPK, IRHS, WMUA developed the manuscript. PK and GWK critically reviewed the manuscript and developed the discussion. All authors read and approved the final manuscript.

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