Journal of Advances in Medicine and Medical Research

26(3): 1-7, 2018; Article no.JAMMR.40923
ISSN: 2456-8899
(Past name: British Journal of Medicine and Medical Research, Past ISSN: 2231-0614, NLM ID: 101570965)

Comparing the Glucose Results by Glucometer and Laboratory Methods: A Prospective Hospital Based Study

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Authors' contributions

This work was carried out in collaboration between both authors. Author OO designed the study, performed the statistical analysis and wrote the first draft of the manuscript. Author RO wrote the protocol and managed the analyses of the study. Author OO managed the literature searches. Both authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JAMMR/2018/40923
Editor(s):
(1) Sevgul Donmez, Faculty of Health Sciences, Gaziantep University, Turkey.
Reviewers:
(1) Dhastagir S. Sheriff, Shri Satya Sai Medical College and Research Institute, India.
(2) Daisy Machado, University of Campinas, Brazil.
(3) Przemyslaw Tomasik, Jagiellonian University, Poland.
Complete Peer review History: http://www.sciencedomain.org/review-history/24289

Original Research Article

Received 6th February 2018
Accepted 16th April 2018
Published 24th April 2018

ABSTRACT

Introduction: Diabetes Mellitus is a rising global concern. Monitoring of blood glucose is an integral part of the management of diabetes. The use of glucometers is prevalent in clinical practice and has beneficial effects. There is need to ensure that reliable results are produced all the time.
Aims: The aim of this study was to compare the glucose level results obtained from the point of care glucometer with that obtained from the laboratory and to establish if there was a statistical significant difference between the two.
Study Design: This is a prospective descriptive study.
Location of Study: This study was conducted in the University of Port Harcourt Teaching Hospital antenatal clinic and the medical out-patient clinic.
Methodology: Fifty patients were selected for the study after institutional ethical committee's

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clearance was obtained. The glucose level of each patient was assayed using both the glucometer and glucose oxidase method with the specimen run in duplicates and measured simultaneously. The results were compared using means, standard deviation, the error of means and correlation.
Results: The means were 4.02 mmol/l and 4.91 mmol/l from set one and 5.02 and 4.22 mmol/L from set two. The variation between the results were 46 and 70% respectively as against the maximum of 20% which is globally acceptable. The standard error of the mean was statistically significant. (p= <0.0001 and <0.001 respectively).
Conclusion: The percentage difference between the two sets of results was greater than the global recommendation. Despite the popularity and ease of glucometer use, standardization and quality assurance are imperative to accurately assessing blood glucose levels.

Keywords: Blood glucose values; glucometer; laboratory values; quality control; diabetes mellitus.

1. INTRODUCTION

Diabetes is a rising global health concern. About 425 million people are living with diabetes worldwide [1]. Most of these individuals, (79%) live in low and medium income countries. It is estimated that by 2045, this number may increase to 629 million [1]. In Nigeria the diabetes prevalence has ranged between 2.9-9% [2,3]. One out of every five persons in sub-Saharan Africa living with diabetes is a Nigerian [4]. The large population of the nation plays a great role in this. The laboratory assessment of venous plasma glucose is the gold standard for making a diagnosis of diabetes mellitus and screening at-risk populations [4].

Glucometers are small handheld devices that can be used to measure capillary blood glucose using just a drop of blood. With advancing technology and the need to increase turnaround time for improved patient management, the use of point of care test (POCT) equipment such as glucometers has gained increasing popularity in this environment. Glucometers are used in the clinics and wards routinely as a form of support for the laboratory. Patients are encouraged to use it for self-monitoring and this is widely accepted [5,6,7]. In some countries, glucometers are used to make a diagnosis of diabetes [8]. However, this is strongly discouraged by some diabetes associations and most endocrine groups in the world [6,7,9].

It has become obvious that the efficient use of glucometers in the clinical and private setting is essential for the effective management of all types of diabetes mellitus including gestational diabetes [6]. Effective glycaemic control is necessary to prevent or reduce the evolution of diabetic complications [6]. Personal involvement of the index patient in the day to day monitoring of glucose is necessary and has been found to be advantageous. It could promote better health-seeking behaviour which would improve lifestyle compliance [1,10]. The resultant effect would be an effective treatment.

Ideally, a glucometer should be evaluated to establish the reliability of its results and how close they are to that of the reference method. Plasma generally has more liquid content than whole blood and tends to give a slightly higher glucose value than whole blood [11]. Although studies have found different degrees of variation between the value of glucometer result and those of the glucose oxidase method, there is, however, an acceptable allowable difference [10-13].

This study aims to assess the concordance of the results of two of the glucometers used in the University of Port Harcourt Teaching Hospital when compared with that obtained from the reference method from the laboratory.

2. MATERIALS AND METHODS

This is a descriptive prospective study conducted in the University of Port Harcourt Teaching Hospital, Nigeria. This study was approved by the ethical committee of the hospital. It is part of a larger study to implement care and advocacy interventions for the management of gestational diabetes. All clients enrolled in the study gave informed consent. They were recruited from the antenatal clinic on their first visit or at 24weeks of gestation, and from the medical outpatient department. Participants were enrolled by convenience sampling method. The agreement between the glucose level results from the glucometers and the laboratory was assessed. A minimum of twenty specimen was required according to the clinical chemistry standard when comparing two methods or evaluating a new method [14]. Fifty specimen were obtained which were both fasting and random. After proper

sterilization, two millilitres of venous blood was obtained from the forearm of the participant and placed in fluoride oxalate specimen tubes. The specimen was sent to the laboratory, centrifuged, separated and assayed. Glucose oxidase method by randox was used to estimate plasma glucose in the laboratory. The glucometers (Fine test and Accu Check) used an electrochemical method involving a variant of the enzyme glucose dehydrogenase that was impregnated into a strip. A drop of blood was taken from the specimen tube, placed on the glucometer strip and read off. Each set of glucometer readings was read by the same trained personnel and the laboratory assay was done by the same experienced Chemical Pathologist. A quality control sample was used with each batch of samples run in the laboratory. This was compared with the expected range from the quality control chart and found to be acceptable, noting the expiry date of the strips. One strip from each of the two vials of test strips was tested against the quality control material provided by the manufacturer to confirm their viability before taking the readings.

All specimen collected had two values, one from the glucometer and the other from the glucose oxidase laboratory method. The data was entered into an Excel sheet and exported to SPSS version 21. Data analysis was done using the means, standard deviations, standard error of means, the paired test and the Pearson's correlation.

3. RESULTS AND DISCUSSION

A total of 50 specimens were measured. Thirty were from the antenatal clinic while 20 were from the medical out-patient clinic. The results range from the reference values in set one was 2.4-7.8 mmol/l with a mean of 4.02 mmol/L while that from the glucometer was 3.3-7.8 mmol/L with a mean of 4.91 mmol/L. In set two, the range from the reference values was 3.2-5.8 mmol/L with a mean of 4.22 mmol/L while that from the glucometer was 3.7-7.1 mmol/l with a mean of 5.02 mmol/L. The raw results are presented in Table 1, the means, standard deviations, standard error of means, paired t test and *P* values are displayed in Table 2, while the correlation is represented in Fig. 1.

This study compared the glucose values obtained from glucometers with that obtained from the reference test method. All fifty reference values were lower than their glucometer counterpart. This finding is not unusual. In a similarly treated/processed sample that is assayed immediately or at the same time, the value obtained from the plasma is usually 10-12% higher than that of whole blood. However in the laboratory where immediate processing is technically not feasible the reverse is the case.

There are various reasons for this observation. The fluoride oxalate tube which is widely accepted for use for obtaining a specimen for glucose analysis contains sodium fluoride and potassium oxalate. The potassium oxalate is the anti-coagulant while the sodium fluoride is the main inhibitor of glycolysis [15]. Glycolysis does not stop immediately because the inhibitor acts on enolase which is the 9th enzyme in the glycolytic chain.

The action of fluoride is fully effective four hours after specimen collection when there is no separation of cells from plasma or serum [15]. This could contribute to a slight variation. It has been established that immediate separation of red cells even with no anticoagulant is more effective than delayed separation in the presence of an anticoagulant. When separated the rate of glycolysis in the first hour is similar with different forms of anticoagulant and even with no anticoagulant. This glycolysis can be reduced by transporting the specimen on ice slush and separating within 30 minutes of specimen collection. This is not practicable in routine clinical practice [16]. When separated, the glucose value remains stable for 8 hours at 25˚C and for 72 hours at 4ºC [15]. A study done in Nigeria found out that at a warmer temperature of 32 degrees, the analysis should be done within the first two hours for best results [17].

Forty-six percent (46%) of the samples in batch one and 70% in batch two had a difference above the acceptable limit. (11) (Table 1) as opposed to the 15% allowable difference.

The International Organization of Standards (ISO 15197:2015) has an expected deviation for glucometer reading when compared to the reference method which is ±0.83mmol/L for values above 5.6mmol/l and 15% for values less than 5.6 mmol/L [10,11,13,18]. Ninety-five percent of readings should fall within this range. The set of readings obtained in this study did not meet these criteria. The p-value obtained from the paired t test in both sets showed that the difference is statistically significant. (Table 2) Fig. 1 shows the correlation.

Table 1. Raw results of glucose in mmol/l measured by the reference method as compared to the POCT glucometer

Reference values	Glucometer values	Difference between the two	Percentage difference
2.4	4.9	2.5	104
2.9	3.5	0.6	20
2.9	5.4	2.5	86
3.2	3.9	0.7	21
3.2	4.1	0.9	28
3.3	4.6	1.3	39
3.5	3.3	0.2	6
3.5	4.6	1.1	31
3.6	4.4	0.8	22
3.6	4.5	0.9	25
3.6	4.6	1	28
3.7	4.8	1.1	30
3.8	4.3	0.5	13
3.8	5.4	1.6	42
3.9	4.6	0.7	17
3.9	5	1.1	28
4	4.2	0.2	5
4	4.4	0.4	10
4	4.8	0.8	20
4.1	5	0.9	21
4.1	5.5	1.4	34
4.2	4.8	0.6	14
4.2	5	0.8	19
4.3	4.6	0.3	7
4.3	4.7	0.4	9
4.3	5.3	1	23
4.4	4.8	0.4	9
6.3	6.8	0.5	8
6.4	7.8	1.4	21
7.4	7.8	0.4	5
3.4	3.7	0.3	9
3.4	3.9	0.5	15
5.8	5.9	0.1	2
3.2	4.2	1	31
4.5	5.5	1	22
5.6	6.6	1	18
3.7	4.3	0.6	16
4	4.9	0.9	23
3.8	4.6	0.8	21
3.4	4.3	0.9	26
4.8	5.7	0.9	19
4.4	5.7	1.3	30
3.2	4.2	1	31
5.8	7.1	1.3	22
4.2	5.2	1	24
3.9	4.3	0.4	10
3.8	5	1.2	31
3	3.9	0.9	30
5.8	6.3	0.5	9
4.6	5	0.4	9

Table 2. Comparison between the values obtained from the reference method and the two glucometer results

	Mean (SD) Reference	Mean (SD) Glucometer	SEM Reference	SEM Glucometer	T-test	*P*-value
1	4.03(±1.03)	4.90(±1.01)	0.189	0.185	8.3296	<0.0001**
2	4.23(±0.93)	5.02(±0.97)	0.207	0.216	10.5662	<0.001**

**SD=Standard deviation P is = 0.5 SEM=Standard Error of the Mean **these values are statistically significant*

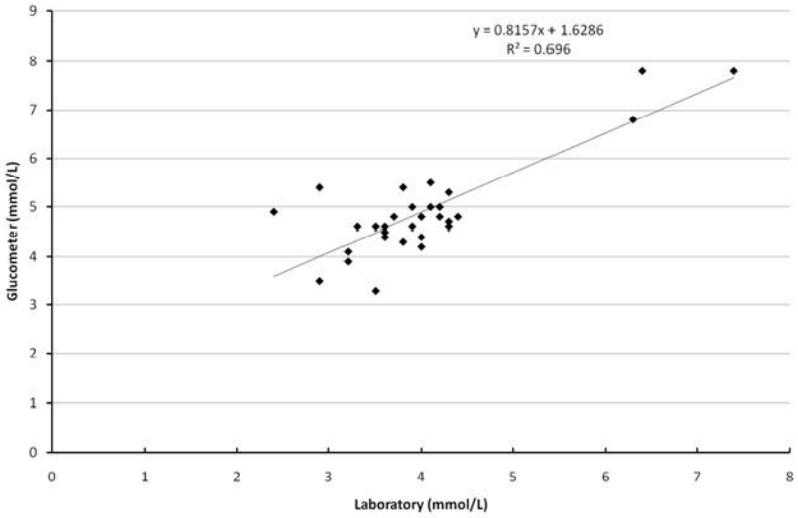

Fig. 1. Correlation between the values obtained from the laboratory reference method and glucometer from the same specimen

Various factors may be responsible for the discrepancy. They include but are not limited to irregularities in the overall process of testing, delay in separation of cells from plasma, use of venous blood and any nonconformity in the laboratory process. Any of the steps involved in providing a reliable result could have been impaired. Glucometer stripes and laboratory reagents are temperature sensitive and can be denatured in extreme temperatures even in storage because they contain enzymes. This has been opined by Tonyushkina et Nichols [11]. Humidity can alter the reliability of strips that use the dehydrogenase enzyme [11]. Therefore the storage condition of the strips influences the output of the glucometer. The age of the test strips could also alter the results [11]. Delay in separation of samples in the laboratory which could be lengthened by delayed transportation could contribute greatly to the difference in results. The presence of polycythaemia and leucocytosis would worsen this difference [11]. To minimize errors during testing, it is therefore important that specimen should ideally be separated within 30-60 minutes of glucometer assay for best results.

In our study, venous blood was used for both methods. Comparing the values of capillary versus venous blood may have been more ideal though it provides a wider and varied range of sources of errors. Most glucometers are however calibrated with capillary blood and using venous blood could alter the result. This effect has been found to be more pronounced in glucose oxidase strips as opposed to glucose dehydrogenase strips [11].

The role of glucometers in the management of diabetes cannot be over emphasized. All patients on insulin treatment are recommended to partake in self-monitoring of blood glucose. (SMDG) [19]. The recent International Federation of Obstetrics and Gynaecology (FIGO) Guidelines for Gestational Diabetes Mellitus Management advocates for routine glucose monitoring [20]. The variations in individual meters and the lack of data as well as challenges in effective quality control are real issues that must be addressed in order to ensure effective patient management. Establishing proper quality control of glucometers is a chief role of the laboratory. We advocate for individual centres to have quality control officers

oversee the use of glucometers in the hospitals. Onsite in clinics, all patients with personal glucometers should be encouraged to present their meters for quality control checks quarterly.

4. LIMITATION OF THE STUDY

This study made use of venous blood. Most glucometers are calibrated with capillary blood. A strategy would be to obtain enough capillary blood to make a comparison.

The variations between capillary and venous blood are more and varied and were eliminated in this study.

5. RECOMMENDATIONS

We recommend that all test apparatus undergo quality checks routinely. Weekly quality control can be done using the quality control material from the manufacturer and laboratory while comparison studies can be done twice a year. This would improve overall patient care. Further studies that compare capillary blood and venous blood as well as one with a larger number of specimen and one that thoroughly investigates all the processes involved in use of both the glucometer and the laboratory are required.

6. CONCLUSIONS

This study shows a significant difference between the glucose values obtained from the glucometers compared to the results obtained from the laboratory. These variations are real issues that must be addressed in order to ensure effective patient management. Establishing proper quality control of all chemistry results produced in the hospital is a chief role of the laboratory. Despite the popularity and ease of glucometer use, standardization and quality assurance is imperative in accurately assessing blood glucose levels. We advocate for individual centres to have quality control officers that oversee the use of glucometers in the hospitals.

CONSENT

Informed consent was obtained from all participants.

ETHICAL APPROVAL

Ethical approval was obtained from the University of Port Harcourt Teaching Hospital research ethical committee.

ACKNOWLEDGEMENT

The authors thank Dr Omosivie Maduka for the assistance during this work.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sciencedomain.org/review-history/24289