 DOI: 10.18231/2394-6377.2017.0002

Comparison of glucose levels using glucometer and GOD-POD Method in diabetic patients

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Abstract

Introduction: Glucometer is widely used at hospitals and homes as a first line tool to get an idea about the current blood glucose levels. Since glucometers are used for making important decisions, it is essential that their accuracy should be comparable to those of standard laboratory analyzers. So the present study was aimed to compare and correlate the glucose levels using glucometer and GOD-POD method in diabetic patients.

Methods: 60 diagnosed type 2 diabetes mellitus patients were selected for the study after institutional ethical committee's clearance was obtained. These were divided into three groups based on their plasma glucose levels by GOD-POD method.

Group 1: 20 Patients having plasma glucose levels ≤ 110 mg/dl.

Group 2: 20 Patients having plasma glucose levels between 111 mg/dl to 250 mg/dl**.**

Group 3: 20 Patients having plasma glucose levels ≥ 251 mg/dl**.**

In this study, we measured plasma glucose levels of each patient simultaneously with glucometer and GOD-POD method (semi-automatic analyzer) in the clinical laboratory.

Results: In our study, we found that that at very high glucose readings (i.e. in group 3 patients having plasma glucose levels ≥ 251 mg/dl), glucometer overestimates glucose results. So, these values do not accurately reflect actual plasma glucose levels.

Conclusions: Very high glucose values obtained using glucometers should be cautiously interpreted and verified with centralized laboratory. The current practice of performing only single readings with glucometers can lead to misdiagnosis. Medical professionals should depict diabetic patients the importance of periodic centralized laboratory glucose testing.

Keywords: Diabetes, Glucose levels, Glucometer, GOD-POD method

Introduction

Blood glucose level control in diabetes mellitus shows a direct relationship with the chances of developing complications. Diabetic patients on insulin therapy require strict monitoring to maintain blood glucose control.[1] Colorimetric/spectrophotometric estimation of plasma glucose using glucose oxidase peroxidase (GOD-POD) method is the gold standard for glucose estimation.[2] Enzymatic GOD-POD method is specific for glucose, but it takes 10-15 minutes of time. Hence, it is not suitable for emergency cases.

Point-of-care testing (POCT) or near patient testing is defined as "Diagnostic Testing that is performed near or at the site of patient care."[3] Self-monitoring of blood glucose (SMBG) is the main tool for diabetes treatment as POCT. SMBG allows patients to measure their own blood glucose levels and to adjust their insulin dose accordingly. The American Diabetes Association (ADA) promotes SMBG to achieve glycemic control in diabetic patients.[4,5]

Rapid measurements of finger prick blood glucose are done by glucometers. Their major advantage is faster turnaround times and use of minimal blood volumes.[6] Glucometer is widely used at hospitals and homes both by medical professionals and patients. They are used as a first line tool to get an idea about the current blood glucose levels. Since glucometers are used for making important decisions, it is essential that their accuracy should be comparable to those of standard laboratory analyzers.[7]

Blood glucose concentrations are roughly 10% to 15% lower than plasma or serum concentrations (plasma or serum has higher water content).[8] Therefore, the International Federation of Clinical Chemistry (IFCC) has recommended that glucometers should report the glucose concentration in plasma.[9] This is to minimize the differences seen in the glucose levels of capillary blood (in SMBG) and plasma (in laboratory).[8]

Performance guidelines have been developed by organizations such as the ADA and the International Standardization Organization (ISO). The ISO guidelines recommend that the accuracy criteria for values <100 mg/dl to ±10 mg/dl and for values ≥100 mg/dl to ±20%.[10] However, the ADA recommends ±5% variation for all values.[11]

So the aim of our study is to check the reliability of results obtained using glucometer in various ranges of glucose level in diabetics.

Aims and Objectives

1. To compare the glucose levels using glucometer and GOD-POD method in diabetic patients.
2. To find the correlation between glucose values estimated using glucometer and GOD-POD method in diabetic patients.

Materials and Methods

The present study was undertaken in the department of Biochemistry, in the tertiary institute. **Duration of study**: 1st Aug to 30th September 2015.

Study design: This is an observational, cross sectional study.

Selection of study subjects:

60 diagnosed type 2 diabetes mellitus patients of age group 30 to 70 and of either sex attending medicine outpatient department (OPD) and/or admitted in ward in the tertiary care hospital and who were ready to participate in the study were selected for the present study. These were divided into three groups based on their plasma glucose levels by GOD-POD method-.

Group 1: (n=20)

20 type 2 diabetes mellitus patients having plasma glucose levels ≤ 110 mg/dl by GOD-POD method.

Group 2: (n=20)

20 type 2 diabetes mellitus patients having plasma glucose levels between 111 mg/dl to 250 mg/dl by GOD-POD method.

Group 3: (n=20)

20 type 2 diabetes mellitus patients having plasma glucose levels ≥ 251 mg/dl by GOD-POD method.

Inclusion criteria: Diagnosed type 2 diabetes mellitus patients of age group 30 to 70 and of either sex.

Exclusion criteria:

a. Acute major illness, recurrent myocardial infarction.
b. Patients who had refused to give informed consent.

Clinical data recording: All the subjects included in the study were evaluated as per the proforma given herewith regarding age, gender, OPD/IPD number and glucose result. The study protocol was approved by the Institutional Ethical Committee (IEC). Informed written consent was obtained from all the study subjects enrolled in the study.

Specimen collection: After taking all aseptic precautions, 5 ml of blood sample was withdrawn from the anti-cubital vein of each participant using sterile needles and syringes without the aid of a tourniquet. Hemolysed samples were excluded from the study. Blood sample from each patient was collected into plain and sodium fluoride bulbs. Plain bulb sample was analyzed by glucometer, while fluoride bulb sample was analyzed by the laboratory GOD-POD method on semi-auto analyzer. The blood samples were analyzed immediately.

Equipments for analysis: Robonik semi-automatic analyzer and Truworth G30 Glucometer

Method of estimation for plasma glucose on semi-automatic analyzer and Glucometer:

GOD-POD method[3]

Principle of GOD-POD method (Semi-automatic analyzer): Glucose oxidase enzyme (GOD) oxidizes the specific substrate beta-D-glucose to gluconic acid and hydrogen peroxide is liberated. Peroxidase enzyme acts on hydrogen peroxide to liberate nascent oxygen (O). Nascent oxygen then couples with 4-amino-antipyrine and phenol to form red quinoneimine dye. The intensity of colour is directly proportional to concentration of glucose in plasma. The intensity of colour is measured colorimetrically at 530 nm and compared with that of a standard treated similarly.

Principle of Truworth G30 Glucometer: Glucometer measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Statistical analysis: Statistical data was recorded on Microsoft excel programme. All the biochemical parameters were presented as mean ± standard deviation (mean ± SD). Statistical analysis was done by using descriptive and inferential statistics using student's paired t test and Pearson's correlation coefficient. The software used in the analysis was SPSS 17.0 version and $p<0.05$ is considered as level of significance.

Observations and Results

The mean plasma glucose levels in group 1 patients by glucometer and by GOD-POD method was found to be 125.80±27.75 and 103.45±23.51 respectively. Similarly in group 2 patients by glucometer and by GOD-POD method was found to be 214.15±34.82 and 185.75±25.95 respectively. In group 3 patients by glucometer and by GOD-POD method was found to be 349.65±47.98 and 287.60±32.30 respectively. p value was found to be 0.001 in all three groups which was statistically significant ($p<0.05$). (Table 1)

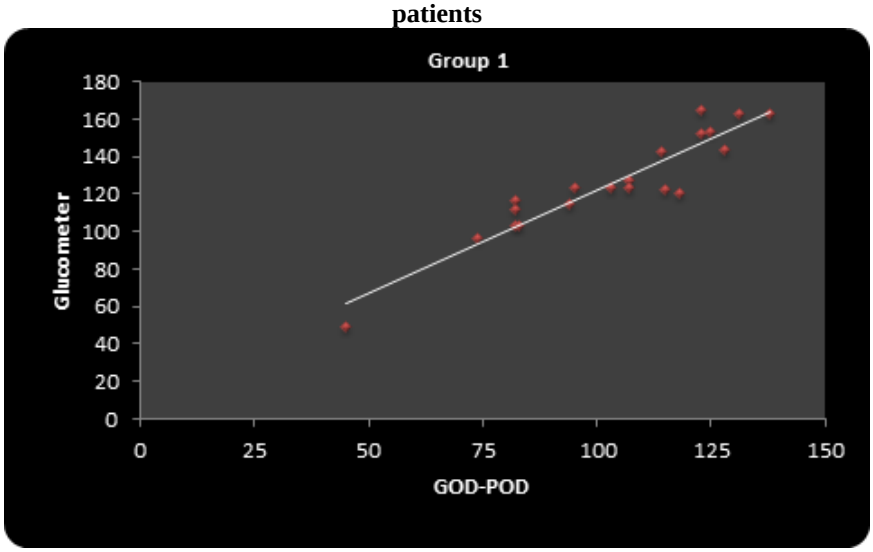
The correlation between plasma glucose values estimated using GOD-POD method and glucometer was found to be 0.93, 0.94 and 0.63 for Group 1, Group 2 and Group 3 respectively. So, correlation between plasma glucose values estimated using glucometer and GOD-POD method in diabetic patients was found to be significantly lower for group 3 patients than those of group 1 and group 2 patients. (Table 1 & Graph 1)

Table 1: Comparison & Correlation between glucose values estimated using glucometer and GOD-POD method in diabetic patients

	Glucometer	GOD-POD	Correlation 'r'	p-value
Group 1	125.80±27.75	103.45±23.51	0.93	0.001, S, p<0.05
Group 2	214.15±34.82	185.75±25.95	0.94	0.001, S, p<0.05
Group 3	349.65±47.98	287.60±32.30	0.63	0.001, S, p<0.05

S-Significance, p<0.05

Graph 1: Correlation between glucose values estimated using glucometer and GOD-POD method in diabetic patients



Discussion

Patients and doctors need a certain level of trust in the results of glucometers. The findings in our study suggested that at very high glucose readings, glucometer can overestimate glucose results. Our study results coincided well with the studies carried out by Reeves ML et al,[12] Khan et al,[13] Baig et al,[14] Clarke et al.[15] The studies mentioned above have also raised the question about the reliability of glucometers especially at extreme values. At these critical hyperglycemic values glucometers show the maximum discrepancies and least correlation with centralized laboratory.[16] Certain preanalytical variables may affect their results.

Glucometer Potential Interferences: (Table 2)

Environmental Factors: Enzymes denature and become inactive at temperature extremes. So, glucometers utilizing enzymes are susceptible to heat and cold. Glucose oxidase glucometers can give falsely elevated glucose values at high altitudes and low temperatures. So, reagents and detector portion (made up of electronics) should be protected from temperature extremes, humidity and moisture.

Physiological Factors: Patients with increased hematocrit (e.g., polycythaemia) can give falsely low glucose values, while patients with low hematocrit (e.g. anemia or diabetic pregnant females) can give falsely high glucose values with glucometer.[17,18] High oxygen tension (patients receiving oxygen therapy) can falsely decrease glucose oxidase glucometer results, while hypoxia can falsely overestimate glucose results.[19,20]

Patients with hypotension (e.g. peripheral circulatory failure and severe dehydration in diabetic ketoacidosis, hyperosmolar non-ketotic coma) may give lower glucose levels with glucometer. Low pH (e.g. diabetic ketoacidosis) can falsely decrease glucometer readings, while high pH elevates glucometer readings.[21,22]

Operational Factors: Approximately 91–97% of overall inaccuracies are due to operational factors.[23,24] The most common reasons are applying insufficient blood sample to the strip, expired strips, strips exposed to excess moisture or humidity, improper code, dirty meters, improper cleaning of the testing site and hemolysed sample.

The limitations of this study are that these glucometers potential interferences were not studied. The study sample was also small and hypoglycemic patients (patients with low blood glucose levels) were not involved in the study.

Substantial difference in performance of glucometers can affect the patient care significantly. In patients of severe hyperglycemia, a falsely elevated glucose reading by glucometer will risk the patient's life because of being overdosed with insulin, which can lead to hypoglycemia. Therefore, medical professionals should always keep in mind these potential falsely

elevated glucose readings by glucometer. They should advice their patients that whenever glucose readings are near the hyperglycemic thresholds by glucometer; verify the results with centralized laboratory, which has the added advantage of quality control as well.

The technique of the user or operator of the glucometer is usually responsible for more inaccuracy than the technical specifications of glucometer itself. So, it is very important that medical personnel & patients utilizing the glucometers should be adequately trained in their usage and maintenance. Physicians, POC workers and clinical Biochemists should evaluate the performance of glucometer periodically.[13,25] This will help to minimize the differences between glucometer and clinical laboratory.

We are not suggesting that glucometers be abandoned. But medical professionals and patients performing the testing should recognize the possibility of failure of such testing. So, readings obtained using glucometers especially at the critical hyperglycemic levels, should be cautiously interpreted and verified with centralized laboratory.

Conclusions

Blood glucose testing with glucometer is a simple, rapid & cost effective method for glucose monitoring. On the other hand centralized laboratory glucose testing despite higher operational time and cost burden is still more reliable method for diagnosis and management of the patient.

Finding in our study suggest that very high glucose values with glucometer do not accurately reflect actual plasma glucose levels; but it overestimates glucose results. So, the routine practice of performing only single testing with glucometers can lead to misdiagnosis. So, readings obtained using glucometers especially at the critical hyperglycemic levels, should be cautiously interpreted and verified with centralized laboratory. Medical professionals should depict diabetic patients the importance of periodic centralized laboratory glucose testing.

A further detailed study for comparison of plasma glucose levels using glucometer and GOD-POD method in hypoglycemic patients with a larger sample size is needed.

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