A Comparative Study of Blood Glucose Level Measurement Between Glucometer and Semi Autoanalyser

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ABSTRACT

Background; Glucometers are the excellent tools for self-monitoring of blood glucose (SMBG). Glucometer is widely used at hospitals and homes as a first line tool to get an idea about the current blood glucose levels. They are important especially in the circumstances where continuous monitoring is mandatory and at decision making levels. **Materials and Methods;** The Study was Conducted in Department of Biochemistry, Civil Hospital Tarn Taran. Proper informed consent was taken from all the participation, a total of 60 sample were taken. **Result;** We found that that at very high glucose readings (i.e. in group 3 patients having plasma glucose levels $\geq$ 251 mg/dl), glucometer overestimates glucose results. So, these values do not accurately reflect actual plasma glucose levels. **Conclusion;** 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.

Keywords: Diabetes, Glucometer, GOD-POD method

I. INTRODUCTION

Glucose is a simple sugar and approximately 4 grams of glucose is present in the blood of humans at all times. Glucose is stored in skeletal muscle and liver cells in the form of Glycogen. Glucose can be transported from the intestines or liver to other tissues in the body via the bloodstream. [1]

The normal fasting plasma glucose ≥6.1mmol/L (110mg/dl) and <7mmol/L (126mg/dl) per WHO 1999 criteria. ADA has choosen a lower cutoff at 5.6mmol/L or 100mg/dl. A persistently high level is referred to as hyperglycemia; low levels are referred to as hypoglycemia. [2] In humans, glucose is the primary source of energy, and is critical for normal function, in a number of tissues. [2] The mammalian brain depends on glucose as its main source of energy [3] , particularly the brain consumes approximately 60% of blood glucose in fasted, sedentary individuals. [1]

A glucose test is a type of blood test used to determine the amount of glucose in the blood. It is mainly used in screening for pre-diabetes or diabetes. [4] Diabetes mellitus (DM), commonly referred to as diabetes, is a group of metabolic disorders in which there are high blood sugar levels are a prolonged period. Diabetes can cause many complications. Acute complications can include diabetic ketoacidosis, hyperosmolar hyperglycemic state, or death.[5] Diabetes and glucose intolerance are diagnosed by measurement of glucose in blood. Glucose is usually measured as venous plasma or capillary whole blood. [6] The post loaded glucose levels in capillary blood were significantly higher than those in venous blood. [7] The estimation of whole blood glucose levels are usually 10-15% lower than plasma glucose alone. The glucose concentration in the water that makes up plasma is equal to that of erythrocytes. Plasma has greater water content than erythrocytes and, therefore, exhibits higher glucose levels than whole blood. [8]

Use of venous derived blood glucose estimation using glucometers designed for capillary blood samples enables rapid treatment decisions during the treatment. The procedure has the advantages of: not requiring a capillary specimen, thereby minimising patient discomfort; decreasing the risks to staff from additional needlestick exposures; and reducing the risk of factitious hyperglycemia from finger pulp glucose contamination. [9] The aim of our study is to check the reliability of results obtained using glucometer in various ranges of glucose level in diabetics.

II. MATERIALS AND METHODS

The Study was Conducted in Department of Biochemistry, Civil Hospital Tarn Taran. Ethical clearance was taken from institutional ethical committee. Proper informed consent was taken from all the participation. 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: 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 65 and of either sex.

Exclusion criteria; Children, Pregnant female, Chronic ill patients, Increased TG patients, Incresed Uric acid patients.

SAMPLE TECHNIQUE/METHOD

Sample of the patients for the investigation of capillary blood glucose and venous blood glucose will be taken after obtaining informed consent. Capillary blood glucose sample will be taken by finger-prick method and reading taken by glucometer. 3 ml of the venous blood sample will be drawn from each subject under aseptic condition. The blood sample will be taken in Sodium fluoride vacutainer for chemical investigation. After 10-15 minutes, sample will be centrifuged at 3000 rpm for 10 minutes to separate plasma. The plasma will be analysed for the biochemical investigation. The data obtained was analysed statistically by computing descriptive statistics, the mean, standard deviation and correlation coefficient. The difference between each method was also calculated.

Principle of Glucometer[10,11] – Glucose meter systems are biosensors that operate on the following general scheme:

Glucose ⎯ Selective membrane Enzyme layer Transducer Amplified, translated screen printing. Glucose is oxidized to gluconic acid and hydrogen peroxide in the presence of glucose oxidase. Hyrogen peroxide further reacts with phenol and 4-aminoantipyrine by the catalytic action of peroxidase to form a red coloured quinoneimine dye complex. Intensity of the colour formed is directly proportional to the amount of glucose present in the sample.

Principle of GOD-POD method (Semi-automatic analyzer)[12]: 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-aminoantipyrine 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.

The present study was Conducted in Department of Biochemistry, Civil Hospital Tarn Taran with an objective to study the of a comparative study of blood glucose level measurement between glucometer and semi autoanalyzer for this purpose, a total of 60 sample were taken.

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 $p<0.05$

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.

Table 1: Comparison between glucose values estimated using Glucometer and Semi Autoanalyser(GOD-POD) method in diabetic patients

	GLUCOMETER	SEMI AUTOANALYSER (GOD – POD)
Group 1	125.80±27.75	103.45±23.51
Group 2	214.15±34.82	185.75±25.95
Group 3	349.65±47.98	287.60±32.30

Table 2: Correlation between glucose values estimated using glucometer and Semi Autoanalyser (GOD-POD) method in diabetic patients

correlation 'r'	p-value
0.93	0.001, S, p<0.05
0.94	0.001,S,p<0.05
0.63	0.001, S, p<0.05

S–Significance, p<0.05

III. RESULTS AND OBSERVATIONS

IV. DISCUSSION

Self-monitoring of blood glucose using reagent impregnated strips is a simple and integral component of Diabetes care and management. The precision and accuracy of glucometers have improved over the years. These glucometer helps the patient to check his or her glucose level at home thus avoiding the need to go to a hospital or a diagnostic lab. In addition, these glucometers also help the physician to determine the glucose level in his or her clinic and provide good quality treatment to the patient.

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. 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,] This will help to minimize the differences between glucometer and clinical laboratory.

V. CONCLUSION

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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Cite this article as :