Is Estimation Of Blood Glucose By Glucometer More Reliable Than Laboratory Analysis? A Comparative Study Done At Rural Hospital Of Maharashtra

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Date of Submission: 12/11/2021

Date of Review: 25/4/2022

Date of Acceptance: 23/5/2022

ABSTRACT

Introduction: Diabetes is a major public health problem that is approaching epidemic proportions globally. Self-monitoring of blood glucose (SMBG) by the American Diabetes Association (ADA) is promoted in diabetic patients so that they achieve and maintain specific glycemic goals.

Objectives : To compare the blood glucose estimation methods; capillary blood and venous blood by glucometer, venous plasma glucose estimation by auto analyzer and to find variation in results.

Material & Methods : 60 patients attending Outpatient department of JIIUs IIMSR and Noor hospital, Warudi, Badnapur, Maharashtra who were advised blood glucose estimation were selected. Finger prick (capillary) blood glucose & glucose estimation of venous blood was done by glucometer; and venous plasma glucose estimation was done by auto analyzer in laboratory.

Result & Conclusion : Mean values of capillary glucose estimation by glucometer were higher than plasma glucose estimation in laboratory on auto analyzer and the difference was found to be statistically significant. Venous glucose estimation on glucometer gave high erroneous results as compared to plasma glucose estimation in laboratory.

KEYWORDS: Autoanalyzer, Bloodglucose, Glucometer, Selfmonitoring of blood glucose

INTRODUCTION:

Worldwide diabetes is a major public health problem that is cause of concern as it is reaching epidemic proportions. ^[1]Blood glucose estimation is the main stay of diagnosis of diabetes mellitus as well as in monitoring of its complications. ^[2] strict glucose monitoring is also essential in management of critically ill patients in ICU. ^[3] Laboratory methods to measure plasma glucose levels are time consuming. Therefore, the use of glucometers has greatly increased. The development of self-monitoring of blood glucose (SMBG) is probably the most important advance in controlling diabetes since the discovery of insulin in the 1900s. Glucose meters are widely used in emergency rooms, outpatient clinics, and ambulatory services and for self-monitoring at home. Glucometers provide rapid blood glucose analysis and allow management of disorders by adjusting glucose to a near-normal range.^[4]

There is a marked variation in glucose level, when estimated from whole blood and plasma; venous blood or capillary blood. It also varies with glucometer method and auto analyzer method. So, it is essential to compare and find out variations in results of different methods of blood collection and methods of estimation.^[5]Clinicians want their glucometer derived glucose results to show close agreement with a plasma laboratory value. There are however challenges in achieving this, which relate in part to physiological differences between these two samples. Although current glucometer systems are accurate, they lack precision and only 95% of results might fall within 20% of the reference plasma laboratory value. Thus the treating doctors must be aware of this, specifically in situations such as patients on insulin pump therapy and diabetes in pregnancy, where the patients and their health care team are aiming for tight glucose control.^[6]

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/dlis+ 10 mg/dland + 20% for values >100 mg/dl^{. [7]} However the ADA recommends a + 5% variation for all values. ^[8] Hence with this study we tried to compare finger prick (capillary) blood glucose & venous blood glucose estimation done by glucometer; and venous plasma glucose estimation done by auto analyzer in laboratory.

MATERIALS AND METHODS :

We selected 60 patients in the age group 18-60 years attending outpatient clinic who were advised blood glucose estimation by physicians. Both diabetic and non diabetic subjects were included in our study irrespective of their prandial status. Those who did not give consent and those having chronic diseases were excluded from the study. After informed consent, capillary sample was collected by finger prick method and estimated by glucometer. Venous blood sample was collected from ante cubital vein and sent immediately to central investigation laboratory of our hospital for estimation on auto analyzer. Venous blood was also used to estimate blood glucose on glucometer.

The glucometer used was One Touch Ultra 2 System for blood glucose monitoring. Special chemicals in the test strip mixes with Glucose in the blood sample producing a small electric current, strength of this current is proportional with the amount of glucose in sample. Glucometer measures the current, calculates the blood glucose level, displays the result, and stores it in its memory. ^[9]In laboratory, the auto analyzer used was ERBA 200 of Transasia which is based on principle of GOD-POD method: 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). (O) Couples with 4-amino antipyrine and phenol to form red quinoneimine dye. The intensity of color is directly proportional to glucose in plasma.

The results of all three estimations were noted on master chart, mean and standard deviation was calculated for all three methods of blood glucose estimation. Student t-test and One way ANNOVA was used, to calculate inter method mean difference, 95% C.I. and p value. p value less than 0.05 was considered to be statistically significant. The study was approved by institutional ethical committee.

Results : Mean age of the patients was 52 + 12 years. Participants included 27 men; 33 women. 32 subjects were known cases of diabetes managed either on oral hypoglycemic drugs or insulin. Remaining 28 were not known cases and came for routine screening or were advised blood glucose estimation for their symptoms. Mean and standard deviation was calculated for all three methods of estimation. The mean and standard deviation for capillary blood glucose by glucometer (CG)was 160.45 + 34.12 mg/dl. For venous blood glucose by glucometer (VG) it was 164.87 \pm 45.24mg/dl. For venous blood glucose by auto analyzer (VA) it was 141.23 + 36.24mg/dl as shown inTable 1

Inter method mean difference value for CG vs VG was 4.42mg / dl (p=0.8075), for CG vs VA (p=0.0200) it was 19.22mg/dl while for VG vs VA it was 23.64mg/dl (p=0.0030). Thus, there was statistically significant difference between capillary glucometer estimation and venous blood glucose estimation on auto analyzer. Difference between capillary and venous blood estimation on glucometer was not

found to be statistically significant while difference between venous blood glucose on glucometer and on auto analyzer was found to be statistically significant. These findings are represented in Table 2

DISCUSSION:

To prevent hypoglycemia and adjust medications, regular monitoring of blood glucose is very essential. In the present study blood glucose concentration estimation is based on three types of sampling. (1) Venous blood sampling estimated by laboratory auto analyzer method. (2) Capillary blood glucose estimated by glucometer and (3) Venous sample estimated by glucometer. In this study, finger prick capillary mean blood glucose by glucometer is higher than venous plasma glucose, estimation done in laboratory method by 19.22 mg/dl. Similar was observed by Boyd et al^[10] (inter method mean difference of 0.58 mmol/L) and Adnan et al [11] (inter method mean difference of 0.84 mmol/L). Patel et al^[12] in their study observed difference of 9.72 mg/dl. Yang et al.^[13] have observed insignificant inter-measurement glucose differences at glucose levels near normal and significant differences at elevated levels Glucose value of a capillary sample is higher than for a corresponding venous sample, because glucose is up taken by tissues as blood flows from the capillaries to the veins, partially depleting the venous sample of glucose. Tissue up take of glucose increases after food. The glucose gradient between capillary and venous samples therefore shows a post prandial increase which may be as high as 20% total glucose concentration.^[14] It also depends of effects of insulin, glucagon, growth hormone and cortisone and also on demand of tissues.^[15] There is also difference between whole blood and plasma values of glucose. In laboratory, we measure the plasma values by auto analyzer, and we measure whole blood by glucometer which are affected by hematocrit values and pH of blood. All these factors should be taken into consideration for comparison of various methods.

This study suggests that capillary blood glucose estimation may not be as reproducible as plasma glucose estimation, however in emergency conditions, incase of OPD diagnosis utilization of finger prick method with glucometer is better alternative to venous blood glucose estimation. Similar was observed in other studies. ^[16, 17] Results of venous plasma glucose estimation by laboratory analyzer and venous whole blood analyses by glucometer method showed marked variation in blood glucose levels. The same was reported by Funk et al., ^[18] Adnan et al ^[11], Patel et al. ^[12] Since glucometers are actually designed for capillary blood, venous blood may give irrelevant & wide variations by glucometer. In routine clinical practice, existing glucometers cannot be used for venous blood samples.

At very high glucose, values with glucometer do not accurately reflect actual plasma glucose levels; but it overestimates glucose results. Hence, the routine practice

Groups	Capillary blood glucose by glucometer (mean \pm SD) CG	Venous blood glucose by glucometer (mean \pm SD) VG	Venous blood glucose by auto analyzer (mean±SD) VA
Average blood glucose Levels	160 ± 34.12	164 ± 45.24	141.23 ± 36.24

Table 1: Comparison of mean and S.D. by all three methods of glucose estimation

Comparison between methods of Estimations	Inter comparison mean difference	95% C.I	P Value
CG vs VG	4.42	-12.336 to 21.1760	0.8075
CG vs VA	19.22	-35.9760 to -2.4464	0.0200*
VG vs VA	23.64	-40.3960 to -6.8840	0.0030*

p value less than 0.05*

Table 2: Inter mean comparison and p value by various methods of estimation of blood glucose

of performing only single testing with glucometers can lead to misdiagnosis. Consequently, 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. ^[19]

CONCLUSION:

Capillary blood glucose estimation by glucometer is an alternative to venous plasma glucose estimation for diagnosis, follow up and in emergency conditions in diabetic and non diabetic patients but the values should be confirmed by plasma glucose estimation in laboratory. Venous blood glucose estimation by glucometer is not advisable. Blood glucose testing with glucometer is a simple, cost effective and rapid method for glucose monitoring. On the other hand laboratory glucose testing despite higher operational time and cost is still more reliable method for diagnosis and management of the patient.

LIMITATIONS:

A further extension of study with larger sample size is needed to compare blood glucose levels by glucometers and auto analyzers.

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How to cite this article: Parveen S, Kausar A. Is Estimation Of Blood Glucose By Glucometer More Reliable Than Laboratory Analysis? A Comparative Study Done At Rural Hospital Of Maharashtra. Perspectives in Medical Research. 2022;10(2):9-12 DOI: 10.47799/pimr.1002.03