

Correlation of Glucometer and Laboratory Blood Glucose Values in a Hospital Set-Up

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Abstract: *The Glucose assay by Chemistry Analyzers in Clinical Biochemistry Laboratory involves various quality checks by trained staff under the supervision of a qualified Biochemistry Professional. But Glucose assay by Glucometer in bedside or critical care or emergency may not involve various quality checks as it is performed by Nursing and Allied Health Science professionals and not directly under the Biochemist. The nature of sample also differs. So there will be a variation in blood glucose values between laboratory testing and Glucometer Testing. This study was conducted to check whether the variation between laboratory testing and Glucometer values were within acceptable range and also to find ways to decrease the variation.*

Keywords: Glucose Assay, Glucometer, Diabetes Mellitus, Point of Care, Clinical Biochemistry Laboratory, Emergency, Nursing

1. Introduction

Diabetes mellitus is characterized by high blood glucose levels (hyperglycemia), polydipsia and polyphagia. It is one of the most common metabolic disorders that is increasing at an alarming rate all over the world^[1-3]. Hyperglycemia needs to be rapidly diagnosed and managed, as prolonged hyperglycemia can lead to dehydration, metabolic disturbances and long-term cardiovascular complications^[4].

Glucometers are widely used in hospitals, outpatient clinics, emergency rooms, ambulatory medical care (ambulances, helicopters, cruise ships) and home self-monitoring. They provide fast analysis of blood glucose levels and allow management of both hypoglycemic and hyperglycemic disorders used in adjusting glucose to a near-normal range, depending on the patient group. Blood glucose testing by Glucometer is one of the most widely performed point-of-care testing (POCT) in a hospital setting^[5].

POCT is a diagnostic test conducted at a place where care is conducted not at the central laboratory. POCT can quickly report results, which can be quickly applied to diagnosis and treatment of patients, contribute to improved patient satisfaction by reducing blood sample volume and meet the needs of clinicians who need to treat more patients^[6]. In hospitals, control of blood glucose in narrow therapeutic ranges plays an important role in preventing complications and lowering the mortality rates attributable to glycemic fluctuations. While central laboratory testing of plasma glucose remains the standard reference, POCT blood glucose test is used widely at the patient bedside because of its reliable quantitative result, portable size, low cost and simple operation^[7, 8]; it enables immediate determination of glucose levels and fast treatment decisions in response to glycemic fluctuations in hospitalized patients.

Glucometers are utilized by a diverse population of patients, representing all ages and acuteness of medical conditions. Both patients and doctors need reliability in the results of glucometers. In keeping with the trend with all medical devices, the Glucometers also have limitations. Establishing

the accuracy of glucometers is challenging^[9]. This study was conducted to check whether the variation between laboratory testing and Glucometer values were within acceptable range and also to find ways to decrease the variation.

2. Material and Methods

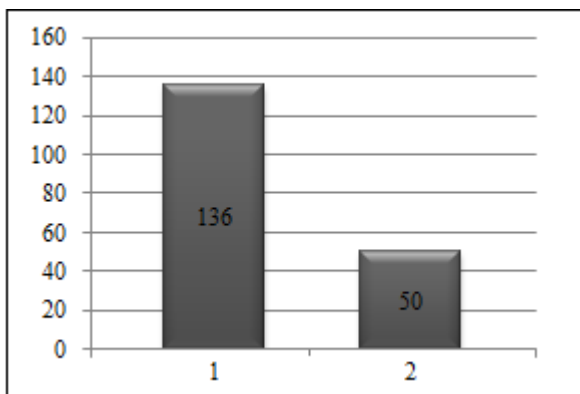
There are 186 blood samples of in-patients from January 2021 to June 2021, who got admitted at Apollo Speciality Hospitals, Vanagaram, Chennai were considered for the study. The samples were taken from all Wards, Critical Care and Emergency Departments. The Reference Criteria as per ISO 15197:2013 (Criteria for Analytical Accuracy) is as follows:

- At Blood Glucose Concentrations of < 100 mg/dL : ± 15 mg/dL
- At Blood Glucose Concentrations of > 100 mg/dL : ± 15 %

The capillary blood sample was used for the Glucometer assay and plasma was used for the assay in Fully automated chemistry analyzer of the Laboratory. The blood glucose assay in clinical biochemistry laboratory was done by DIRUI 1300B Auto Chemistry Analyzer - GOD-POD Enzymatic method and the Glucometer used was ACCU-CHEK Performa - works based on electrochemical method.

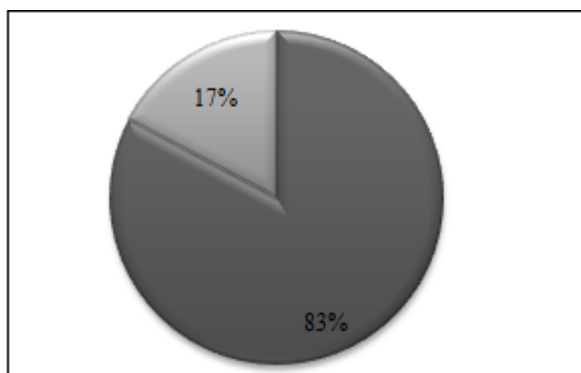
3. Results

Among 186 samples analyzed for blood glucose, 136 were more than 100 mg/dL and 50 were less than 100 mg/dL (Fig 1). The difference in Glucometer values were: Beyond ± 15 % = 32 (17 %) Within ± 15 % = 154 (83 %) (Fig 2)



Blood Glucose 1. > 100 mg/dL; 2. < 100 mg/dL

Figure 1: Number of samples tested (Initial Audit)



Beyond $\pm 15\%$ = 32 (17 %) Within $\pm 15\%$ = 154 (83 %)

Figure 2: Difference in Glucometer Values (Initial Audit)

4. Discussion

Diabetes is a chronic carbohydrate metabolism disorder that require continuous blood glucose monitoring. The two common methods used for blood glucose measurement are the bedside glucometer, and laboratory-based chemical analyzer, each of these methods has its advantages and disadvantages. The most important aspect of these methods is their accuracy in determining the exact blood glucose level.

The central laboratory testing of plasma glucose remains the standard reference, POCT blood glucose test is used widely at patient bedside because of its reliable quantitative result, portable size, low cost, simple operation and mainly for quick diagnosis for initiating the treatment within less turn-around time. But wherever POCT Glucose Assay using Glucometer is performed, there has to be monitoring is required for regular calibration, quality control check, following of standard operating procedures, validation and the competency of staff who are performing the test. By following this POCT Glucose assay by Glucometer can be considered as an accurate assay used for patient care.

In our study, among 186 samples analyzed for blood glucose, 136 were more than 100 mg/dL and 50 were less than 100 mg/dL and the difference in Glucometer values were as follows, (a) Beyond $\pm 15\%$ = 32 (17 %) (b) Within $\pm 15\%$ = 154 (83 %). The cause in this difference may be due to various factors. There are many studies which have pointed out factors causing difference in values, i.e., Operator competency is important to POCT quality because

it is one of the potential sources of error^[10]; Cleaning and disinfection of glucometer should be performed to prevent transmission between patients^[11] and has to be a routine practice after each use, regardless of whether it has been shared between patients^[12]; Temperature and humidity are common factors that affect the glucometer measurements^[13]; the enzymes on the strip can be inactivated at extreme temperature while exposure to humidity can prematurely rehydrate the enzyme and limit its reactivity during for patient testing^[14]; In pre-analytical phase, a higher rate of errors such as patient identification was found in POCT compared to central laboratory testing^[15]. In analytical phase, delay in testing due to an operator not being certified to perform testing was reported as the most common error related to POCT glucose test^[16]; In the postanalytical phase, even if the clinician is immediately knowing the results, possibilities of errors is there in manual entry^[17]. Considering the various factors, the competency plays an important role to reduce the deviation in results.

5. Conclusion

The Glucose assay by Chemistry Analyzers in Clinical Biochemistry Laboratory involves various quality checks by trained staff under the supervision of a qualified Biochemistry Professional. But Glucose assay by Glucometer in bedside or critical care or emergency may not involve various quality checks as it is performed by Nursing and Allied Health Science professionals and not directly under the Biochemist. The nature of sample also differs. So there will be a variation in blood glucose values between laboratory testing and Glucometer Testing. Considering the various factors, the competency of users by training has to be increased for accuracy in reports.

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