

Original Article

# Role of Pathology and Point of Care Testing in the Estimation of Fasting Blood Glucose Levels in Type 2 Diabetes Mellitus Patients

Zainab Yousaf<sup>1\*</sup>, Sania Ahmed<sup>2</sup>, Muhammad Raza<sup>3</sup>, Shamaila Rashid<sup>4</sup>, Saba Qasim<sup>5</sup>, Muhammad Touqeer Hanif<sup>6</sup>

<sup>1</sup>Lab Manager, Department of Pathology, Farooq Hospital Westwood, Lahore, Pakistan.

<sup>2</sup>Medical Technologist, Department of Pathology, Farooq Hospital Westwood, Lahore, Pakistan.

<sup>3</sup>Lecturer, MLT department Minhaj University, Lahore, Pakistan.

<sup>4</sup>Medical Technologist, Department of Pathology, Farooq Hospital Westwood, Lahore, Pakistan.

<sup>5</sup>Assistant Professor, University of Management & Technology, Lahore, Pakistan.

<sup>6</sup>Senior Lecturer, College of Allied Health Sciences, Akhtar Saeed Medical & Dental College, Lahore, Pakistan.

\*Corresponding Author: Zainab Yousaf, Lab Manager; Email: zainabyousaf00@gmail.com

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## ABSTRACT

**Background:** Diabetes mellitus (DM) is a global health concern with significant morbidity and mortality. Effective management of type 2 DM necessitates accurate monitoring of fasting blood glucose levels. Traditional laboratory methods, while accurate, are not always convenient for patients, leading to a growing interest in reliable point-of-care testing.

**Objective:** The aim of this study was to compare the accuracy of fasting blood glucose measurements between point-of-care testing using a glucometer and traditional laboratory methods (hexokinase and end-point) to determine the feasibility of home-based patient monitoring.

**Methods:** This comparative cross-sectional study included 150 type 2 DM patients from Farooq Hospital Westwood, Lahore. Participants underwent fasting blood glucose testing using three methods: the hexokinase method, the end-point method, and a glucometer (Accu-check instant S Meter). The Pearson correlation was employed to assess the linear relationship between the methods, while multivariate ANOVA was used to compare the means.

**Results:** The Pearson correlation coefficients indicated a strong positive correlation between the glucometer readings and both laboratory methods, with coefficients of 0.994 for hexokinase and 0.997 for the end-point method. The average fasting blood glucose levels measured were 128.43 mg/dL ( $\pm 61.257$ ) for hexokinase, 128.59 mg/dL ( $\pm 61.110$ ) for the end-point method, and slightly lower at 123.59 mg/dL ( $\pm 58.920$ ) for the glucometer.

**Conclusion:** The study concluded that glucometer readings are highly correlated with traditional laboratory methods, indicating that point-of-care testing can be a reliable alternative for patients to monitor fasting blood glucose levels at home.

**Keywords:** Type 2 Diabetes Mellitus, Fasting Blood Glucose, Hexokinase Method, End-Point Method, Glucometer, Point-of-Care Testing.

## INTRODUCTION

Diabetes mellitus (DM) is a longstanding health challenge that has been recognized for millennia, with a rich history of scientific inquiry into its diagnosis and management. The quest to understand and treat DM has engaged many of the finest minds in the history of medicine, underscoring the complexity and persistence of this condition across both developed and developing nations (1, 2). The pathophysiology of DM involves the breakdown of ingested food into glucose, which is then released into the bloodstream. Insulin, a hormone produced by the pancreas, plays a critical role in this process by facilitating the entry of glucose into cells. However, in individuals with DM, this mechanism is compromised due to insufficient insulin production or ineffective utilization, leading to elevated blood glucose levels. These elevated levels, if not managed, can precipitate a range of severe complications (3, 4).

Type 2 DM, the most prevalent form of the disease, is characterized by high blood glucose levels resulting from inadequate insulin production by the pancreas. This leads to an accumulation of glucose in the bloodstream, as it cannot be efficiently transported into cells. Symptoms of type 2 DM include increased thirst and urination, heightened hunger, blurred vision, non-healing sores, and unexplained weight loss, with risk factors including overweight, obesity, genetic predisposition, and insulin resistance. The development of long-term complications is a significant risk with type 2 DM, which may emerge as the initial presenting symptom in previously undiagnosed individuals (5-7).

The critical role of fasting blood glucose testing in the diagnostic and management paradigm of type 2 DM cannot be overstated. Elevated fasting blood glucose levels serve as a harbinger of impaired fasting glucose or overt DM, thereby enabling prompt intervention. Furthermore, this testing modality is instrumental in identifying individuals with prediabetes, a condition marked by blood glucose levels that exceed normal values but fall short of the diabetic threshold. The early detection of prediabetes is crucial, as it opens the door for lifestyle modifications aimed at thwarting the progression to DM. According to the American Diabetes Association (ADA), the diagnosis of type 2 DM is confirmed when specific criteria are met, including fasting blood glucose levels (8-11).

The present study endeavors to compare three distinct methodologies for the estimation of fasting blood glucose levels in patients with type 2 DM, to enhance patient care. These methodologies encompass the hexokinase (Innoline) method, the end-point (Innoline) method, and glucometer-based assessments (Accu-Check Instant S Meter), each characterized by its own specificity and sensitivity (12). The objective of this comparative analysis is to elucidate the most effective approach for the estimation of fasting blood glucose, thereby facilitating optimal management strategies for individuals grappling with type 2 DM. This endeavor reflects the ongoing commitment to refining diagnostic and therapeutic interventions for DM, in alignment with the historical and contemporary challenges posed by this pervasive health issue.

## MATERIAL AND METHODS

This study was a comparative cross-sectional analysis conducted at Farooq Hospital Westwood, Lahore, employing a convenience sampling strategy to enroll participants. The research aimed to compare the efficacy of three different methods for estimating fasting blood glucose levels in patients diagnosed with type 2 diabetes mellitus (DM). A total of 150 individuals were included in the sample, selected based on a confidence level of 90%, a margin of error of  $\pm 5\%$ , and an anticipated prevalence rate of 5%. The inclusion criteria were patients with type 2 DM who adhered to standard fasting protocols, requiring a fasting period of at least 8 hours but no more than 16 hours prior to blood collection. Exclusion criteria included patients who had provided repeat samples or those diagnosed with any systemic diseases other than type 2 DM (13).

A specifically designed questionnaire, serving as a medical history form, was utilized to gather data from the participants. This study measured fasting blood glucose levels using three distinct methods: the hexokinase and end-point methods (both Innoline), and a glucometer measurement (Accu-check instant S Meter). For glucometer readings, blood glucose levels were quantitatively assessed in fresh capillary whole blood drawn from the finger, palm, forearm, or upper arm, employing biosensor technology. The Accu-check instant test strips, used in conjunction with the Accu-check instant S Meter, facilitated these measurements. The strips, which came with specified lot numbers and expiration dates, provided results displayed on the glucometer's digital window (14). Results were categorized based on the target range preset by the manufacturer (70-160 mg/dL), with blue indicating a result above the target range, green within, and red below.

In parallel, approximately 3ml of venous blood was collected into Sodium fluoride vacutainers for each participant and dispatched to the chemical pathology laboratory for analysis. Plasma separation was achieved through centrifugation at 3000 rpm for 10 minutes, followed by glucose level analysis using both the end-point and hexokinase methods on an automated chemistry analyzer (SELECTRA-PRO M). To ensure accuracy, internal and external quality controls were implemented alongside the test samples.

The principles underlying glucose determination by the end-point and hexokinase methods were detailed through schematic representations, elucidating the biochemical reactions involved in each process.

Data collection adhered to the ethical guidelines stipulated in the Declaration of Helsinki, ensuring all participants provided informed consent before inclusion in the study. Ethical approval was obtained from the institutional review board of Farooq Hospital Westwood, Lahore, affirming the study's adherence to ethical standards in medical research.

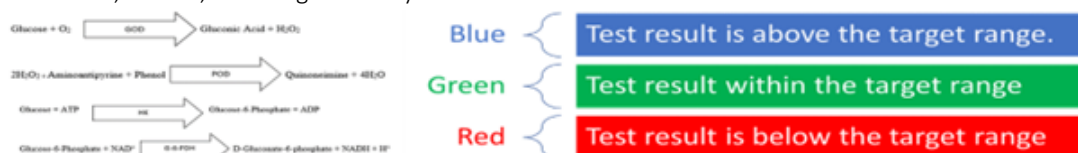


Figure 1: End-point glucose determination; Figure 2: Hexokinase glucose assay.

Data analysis was conducted using the Statistical Package for the Social Sciences (SPSS) version 25.0. Quantitative variables, such as age, were summarized using mean and standard deviation, while categorical variables were expressed in frequencies and percentages. The estimated marginal means of fasting plasma glucose were computed utilizing multivariate ANOVA, and the linear relationship between the different methods of glucose measurement was examined through two-tailed Pearson correlation analysis. This comprehensive approach to data collection and analysis aimed to ensure the reliability and validity of the study's findings, contributing valuable insights into the comparative efficacy of fasting blood glucose estimation methods in the management of type 2 DM.

## RESULTS

In the study, the fasting blood glucose levels measured by the hexokinase method, the end-point method, and glucometer readings exhibited strong positive correlations, as evidenced by the Pearson correlation coefficients. The hexokinase and end-point methods demonstrated an almost perfect correlation with a coefficient of 0.998, indicating that the values obtained by these two methods are almost identical. This correlation was highly significant with a two-tailed p-value of 0.001, well below the 0.01 level, suggesting a less than 0.1% probability that this strong correlation is due to random chance in a sample size of 150.

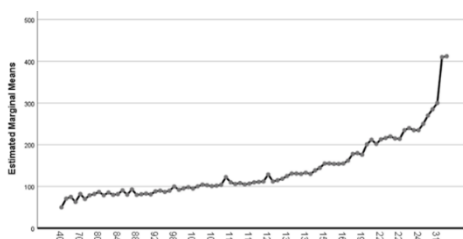
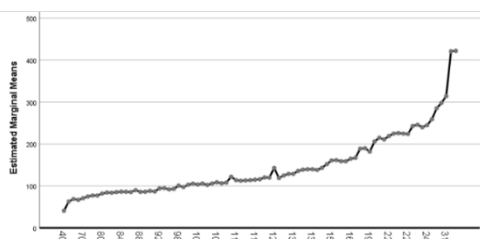
Similarly, the hexokinase method and the glucometer readings showed a very high correlation, with a Pearson coefficient of 0.994. The significance of this correlation was also marked by a p-value of 0.001, which underscores the reliability of the glucometer readings when compared to the laboratory-based hexokinase method. The end-point method and glucometer readings were closely aligned as well, with a Pearson coefficient of 0.997 and the same level of significance.

Table 1 Correlation Matrix of Glucose Measurement Methods

	Hexokinase	Endpoint	Glucometer
<b>Hexokinase</b>			
<b>Pearson Correlation</b>	1	0.998**	0.994**
<b>Sig. (2-tailed)</b>		0.001*	0.001*
<b>N</b>	150	150	150
<b>Endpoint</b>			
<b>Pearson Correlation</b>	0.998**	1	0.997**
<b>Sig. (2-tailed)</b>	0.001*		0.001*
<b>N</b>	150	150	150
<b>Glucometer</b>			
<b>Pearson Correlation</b>	0.994**	0.997**	1
<b>Sig. (2-tailed)</b>	0.001*	0.001*	
<b>N</b>	150	150	150

\*\*\* signifies a significant correlation at the 0.01 level (2-tailed).  
 \*\* indicates significance at the 0.05 level (2-tailed).  
 "N" denotes the sample size (150 for each method).  
 Pearson correlation coefficient values range from -1 to +1, showing the strength and direction of a linear relationship between variables.  
 A Sig. (2-tailed) of 0.001 or less denotes a highly significant correlation, suggesting a strong likelihood that the correlation is not due to chance.

This indicates that the glucometer, a more accessible point-of-care tool, is nearly as accurate as the sophisticated laboratory methods for measuring fasting blood glucose levels in this sample of type 2 diabetes mellitus patients.



The graphs both illustrate scatter plots of glucose measurements obtained via the hexokinase (HK) method (x-axis) against estimated marginal means (y-axis). In each graph, the data points maintain a steady trajectory at lower HK glucose levels, then sharply increase once glucose HK levels exceed

approximately 300 mg/dL. This rise continues steeply, peaking at the highest recorded HK glucose level around 600 mg/dL, indicating a strong positive correlation between the HK glucose levels and estimated marginal means, particularly in the upper range of glucose values. The similarity in patterns between the two graphs suggests consistent results across two sets of measurements or analyses. These statistical correlations confirm the consistency and reliability across the three methods tested, with strong linear relationships and highly significant p-values indicating that the observed correlations are indeed genuine and not due to random variation. With each method's results corroborated by the others, the findings suggest that all three methods are robust for measuring fasting blood glucose levels in a clinical setting, offering both precision and practicality for monitoring and managing type 2 diabetes mellitus.

## DISCUSSION

The study under consideration explored the correlation between traditional pathology testing and point-of-care testing to ascertain fasting blood glucose levels in patients with type 2 diabetes mellitus (DM). Pathology testing, a cornerstone in the diagnosis and management of various medical conditions, relies on the analysis of blood samples to detect biochemical imbalances indicative of specific diseases. Despite its utility, conventional pathology testing necessitates that patients visit a laboratory, which may not always be feasible, particularly for those with mobility issues (15). Point-of-care testing, which involves diagnostic procedures conducted at or near the patient's location, offers a rapid alternative, yielding immediate results that can significantly influence patient care decisions. This is especially pertinent in critical care settings such as emergency departments or intensive care units, where swift diagnostic outcomes are crucial (16).

The current investigation juxtaposed point-of-care testing, using a glucometer, with two spectrophotometric methods—hexokinase and end-point assays—to evaluate whether these approaches yielded correlated results for fasting blood glucose, thereby facilitating easier monitoring for patients with type 2 DM (17). The findings revealed a positive correlation among the three testing methods, resonating with the outcomes of Kathmandu et al., and Ayyaanar et al., which also reported positive correlations between hexokinase and end-point methods (18, 19). The study's results indicated elevated fasting blood glucose levels in type 2 DM patients across all methods, with no significant variance in the means between the endpoint and hexokinase methods. However, the glucometer readings were slightly lower, which could be attributed to differences in sample matrices—whole blood for glucometers versus plasma for laboratory tests (20).

While pathology testing is generally deemed more reliable due to rigorous quality control procedures, point-of-care testing, when performed with validated instruments, presents a viable alternative for regular monitoring (21). In this context, the study confirmed a positive correlation between the glucometer readings and the two laboratory-based methods, albeit within the limitations of the specific devices and reagents used—Accu-check instant S Meter and Innoline, respectively. Future research should expand upon these findings, exploring the correlation between other glucometers and reagents across larger patient cohorts to validate the generalizability of these results.

In conclusion, the study established that the hexokinase method, considered the gold standard for glucose measurement, and the end-point method were in close agreement with the glucometer readings for assessing fasting blood glucose in type 2 DM patients. This suggests that patients with type 2 DM can reliably monitor their fasting glucose levels using a glucometer, facilitating more consistent disease management.

In acknowledgment, gratitude is extended to the patients whose participation was instrumental to the study and to the hospital staff who assisted in the collection and processing of samples. The study's strength lies in its practical implications, offering an alternative to laboratory testing for patients. However, it is not without limitations—the study's applicability is restricted to the glucometer and reagents specified. Therefore, broader research is recommended to examine the correlation with other devices and reagents, which could strengthen the reliability of point-of-care testing for a wider patient population.

## CONCLUSION

In conclusion, the study established that point-of-care testing using a glucometer is comparably accurate to the hexokinase and end-point methods in measuring fasting blood glucose levels in type 2 diabetes mellitus patients. This finding implies that individuals with type 2 DM have the flexibility to reliably monitor their condition at home, which could lead to better disease management, increased patient autonomy, and potentially lower healthcare costs due to reduced dependency on laboratory testing. Such accessibility to accurate glucose monitoring is particularly crucial for patients in remote areas or for those with limited mobility, thereby enhancing the overall quality of diabetes care.

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