CORRELATION BETWEEN POINT-OF-CARE AND LABORATORY-BASED AUTOMATED BLOOD GLUCOSE TESTING

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ABSTRACT

Background: Diabetes mellitus is a growing global health concern, with rising prevalence particularly in low- and middle-income countries. Accurate blood glucose estimation is essential for diagnosis, monitoring, and prevention of complications. While glucometers provide rapid, convenient results at the point of care, laboratory autoanalyzer are considered more reliable. This study aimed to compare the accuracy and correlation between these two methods.

Methodology: A comparative study was conducted on 150 patients above 18 years, including both diabetic and non-diabetic individuals. Capillary blood glucose was measured using a glucometer via finger prick, while venous blood samples were analysed using a laboratory autoanalyzer. Statistical analysis done by paired t-test.

Result: The mean blood glucose level obtained from the glucometer was approximately 8.49 mg/dL higher than that of the autoanalyzer. A strong positive correlation was observed ($r = 0.959$), indicating that both methods follow a similar trend. However, the paired t-test ($t = 4.68$, $p < 0.001$) showed a statistically significant difference.

Discussion: The findings indicate that glucometers tend to overestimate glucose levels, consistent with previous studies. This discrepancy may arise due to operational errors such as expired strips, improper sample handling, or device calibration issues. Such inaccuracies can lead to inappropriate clinical decisions, especially in critical glycemic conditions.

Conclusion: Although glucometers are useful for routine monitoring and point-of-care testing, they are not fully interchangeable with laboratory methods due to significant bias. Laboratory autoanalyzers remain the gold standard for accurate glucose estimation.

Keywords: Diabetes Mellitus, Glucometer, Autoanalyzer, Blood Glucose Estimation.

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Over time, it has become one of the most significant global health concerns, with its prevalence steadily increasing across both developed and developing nations. This rise is largely driven by factors such as urbanization, sedentary lifestyle, unhealthy dietary patterns, increasing obesity, and an aging population.[1]

As diabetes is a long-term condition associated with multiple complications, its effective diagnosis and management depend heavily on accurate measurement of blood glucose levels.

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Monitoring blood glucose is a fundamental aspect of diabetes management and plays a key role in guiding therapeutic decisions. Persistent hyperglycemia contributes to the development of microvascular complications such as retinopathy, nephropathy, and neuropathy, as well as macrovascular complications including coronary artery disease and stroke.[2] Large clinical trials have demonstrated that maintaining optimal glycemic control significantly reduces the risk of these complications and improves overall outcomes.[3] Therefore, precise and reliable estimation of blood glucose is essential not only for diagnosis but also for ongoing monitoring and prevention of disease progression.

In routine clinical practice, laboratory-based methods are regarded as the gold standard for glucose estimation. Automated chemistry analyzers, commonly using enzymatic methods such as glucose oxidase or hexokinase, provide highly accurate and reproducible results.[4] These methods are supported by stringent quality control measures and standardized calibration systems, minimizing analytical variability. However, despite their accuracy, laboratory methods have certain limitations, including the need for trained personnel,

sophisticated equipment, and longer turnaround times, which may not be ideal in emergency situations.[5]

To address these limitations, point-of-care testing (POCT) devices such as glucometers are widely used in both hospital and home settings. These devices are portable, easy to use, and provide rapid results using capillary blood obtained via finger prick. Their convenience and quick turnaround time make them particularly useful for self-monitoring and bedside testing.[6] In emergency and critical care settings, glucometers enable immediate assessment of blood glucose levels, allowing prompt clinical intervention.[7]

Despite these advantages, concerns remain regarding the accuracy and reliability of glucometer readings when compared to laboratory-based measurements. Several factors can influence glucometer performance, including hematocrit variations, environmental conditions such as temperature and humidity, interfering substances, and user-related factors like improper sampling technique or inadequate blood volume.[8] These variables may lead to discrepancies between capillary glucose values obtained from glucometers and venous plasma glucose levels measured by laboratory autoanalyzers. Such differences can be clinically significant, especially near diagnostic cut-off values or in critically ill patients.[9]

Even minor inaccuracies in glucose measurement can have important clinical consequences. Studies have shown that erroneous glucometer readings may result in inappropriate insulin dosing, leading to hypoglycemia or poor glycemic control.[1] To address these concerns, international standards such as ISO 15197:2013 define acceptable accuracy limits for blood glucose monitoring systems.[11] However, variability in device performance has been reported, indicating that not all glucometers consistently meet these criteria.[12–14]

Furthermore, in hospitalized or critically ill patients, glucometer reliability may be affected by altered physiological conditions such as impaired peripheral perfusion, variations in oxygen tension, hematocrit changes, and drug interference.[15] These factors underscore the importance of correlating glucometer readings with laboratory-based measurements, particularly when precise glucose estimation is critical for clinical decision-making.

Although glucometers are widely used in clinical practice and for self-monitoring, questions regarding their accuracy in comparison with laboratory-based methods continue to exist. Establishing the extent to which glucometer readings correspond with laboratory measurements is important, particularly in situations where treatment decisions depend on precise glucose values.

Therefore, the present study was designed to compare blood glucose levels measured using a portable glucometer with those obtained through a laboratory autoanalyzer and to assess the level of agreement between the two methods.

Aim & Objectives

- To compare the blood glucose values obtained using a glucometer and a laboratory autoanalyzer.
- To analyse the correlation between the two methods.

MATERIAL & METHOD

A Comparative analysis was on 150 patients blood glucose samples measured using a portable glucometer and a laboratory – based autoanalyzer in the Postgraduate Department of Biochemistry, ASCOMS & Hospital, Jammu.

Inclusion Criteria

- Patients above 18 years, both sexes, with or without T2DM.

Exclusion Criteria

- Patients below 18 years.

Sample Collection

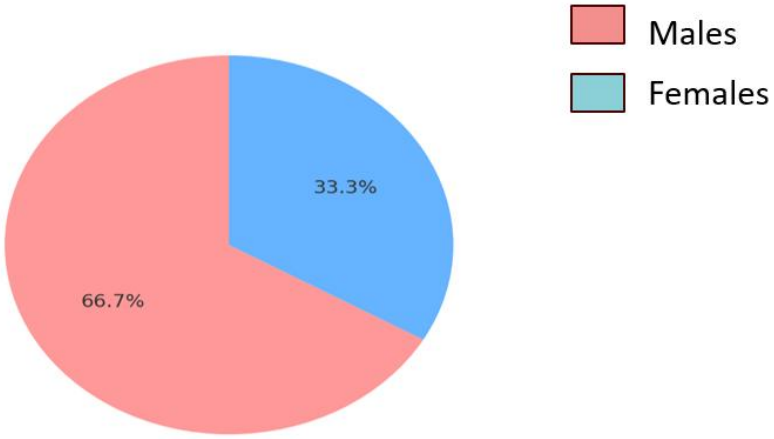
Capillary glucose measured by glucometer; finger prick, venous blood (3 mL) collected in sodium fluoride vacutainers and analyzed using an autoanalyzer (Roche) by hexokinase method.

Statistical Analysis

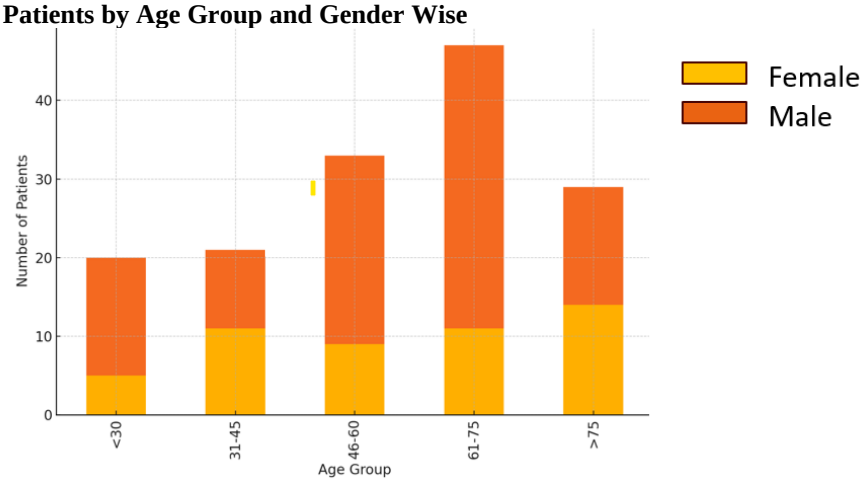
Data analyzed using mean, SD, correlation coefficient, and Student's t-test.

RESULTS

Gender-Wise Distribution of Patients



Distribution of Patients by Age Group and Gender Wise

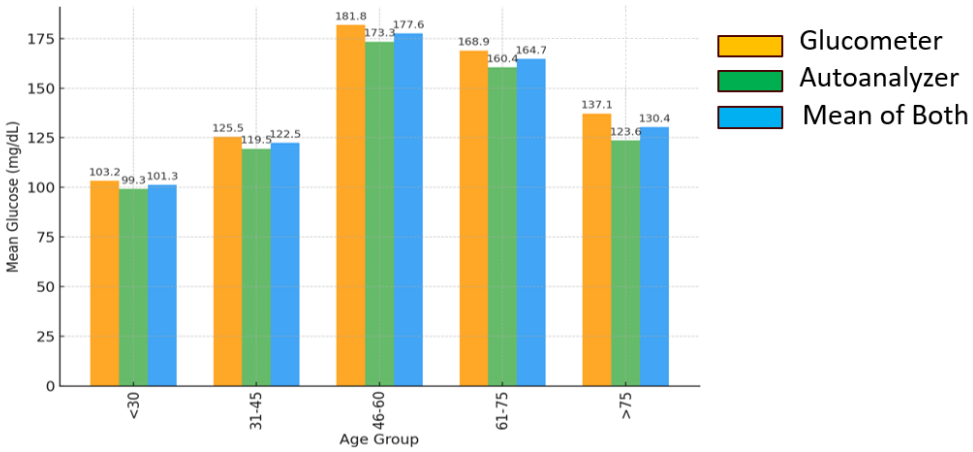


Mean Blood Glucose Levels by Age Group:

Age Group (years)	Glucometer (mg/dl)	Autoanalyzer (mg/dl)	Mean Glucose
<30	103.25	99.30	101.28
31–45	125.48	119.48	122.48
46–60	181.76	173.33	177.55
61–75	168.89	160.40	164.65
>75	137.14	123.62	130.38

- This indicated the glucometer readings for each age group are higher than corresponding autoanalyzer readings.

Mean Blood Glucose Levels by Age Group (graphical representation)



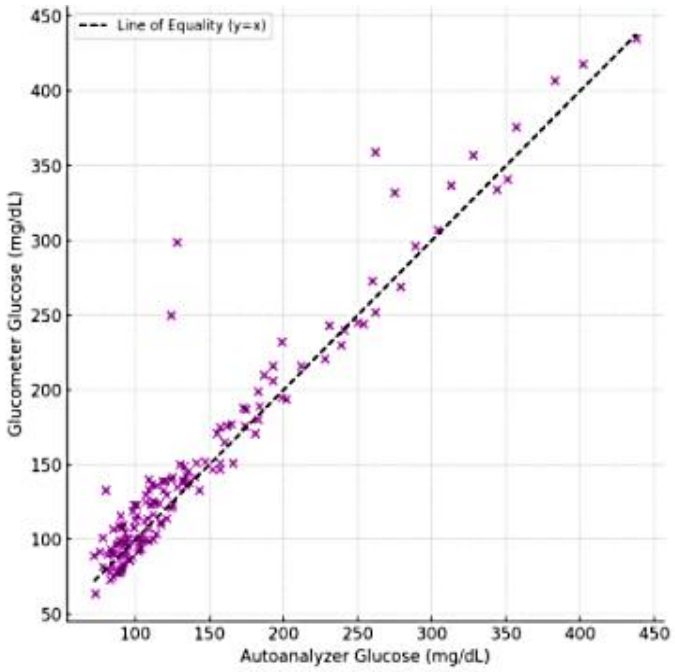
Comparison of Blood Glucose by Glucometer and Autoanalyzer:

Parameters	Glucometer	Autoanalyzer
Mean glucose (mg/dl)	150.75	142.26
Standard deviation (mg/dl)	78.56	74.07
Sample size (n)	150	
Mean difference	≈ 8.49	
Standard deviation	22.23	

- The mean blood glucose level measured by the glucometer was approximately **8.49 mg/dL higher** than the laboratory autoanalyzer readings, indicating a tendency of the glucometer to yield **higher glucose estimates**.

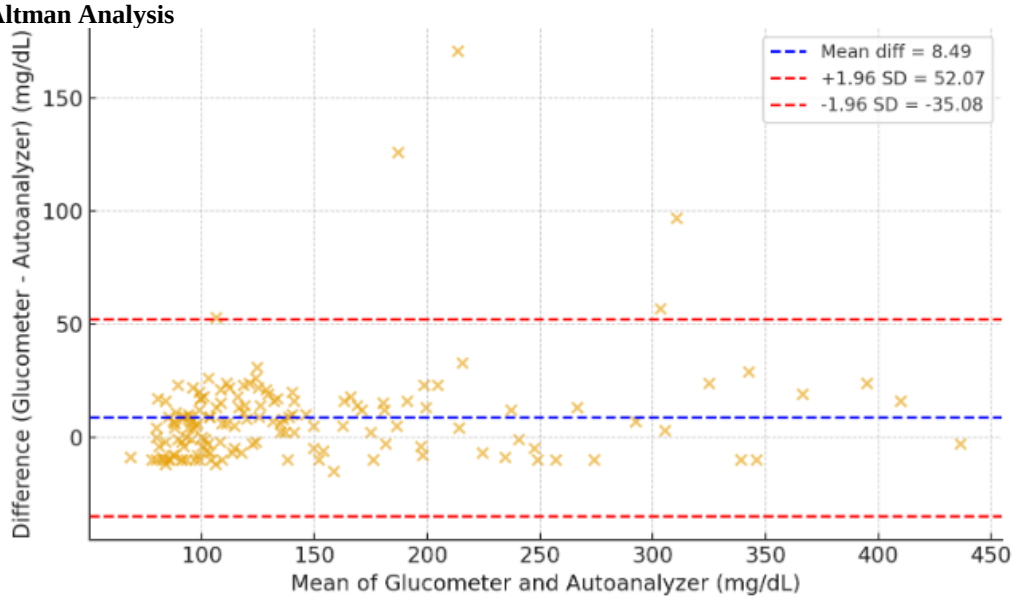
Correlation between Glucometer and Autoanalyzer Readings

- **Correlation Analysis**
  - The Pearson correlation coefficient (r) between glucometer and autoanalyzer readings was **0.959**, denoting a very strong positive correlation.
  - This implies that the two measurement techniques track blood glucose levels in a similar linear pattern, although their absolute values differ.



- Paired t-test was applied to compare both datasets, yielding:
- **t-statistic**: 4.68
- **p-value**: < 0.001
  - This indicates that the difference between the two methods is statistically highly significant.
  - The higher readings observed with the glucometer are therefore unlikely to be due to random error.

Bland – Altman Analysis



- The glucometer consistently overestimated glucose values with moderate agreement on Bland–Altman analysis.

DISCUSSION

In our present study, blood glucose levels measured using glucometer and laboratory Autoanalyzer, showed the mean difference was approximately;**8.49 mg/dl** ± **22.23** which was correlated with the study done by **Boyd et al** - who observed the mean difference was **10.4 mg/dl** [(16)].Another study done by **Sato et al** – also observed the mean difference was **10.2 mg/dl**.[(17)].This revealed that there is a tendency of glucometer to yield higher glucose

estimates.The Huge gap resulting in inappropriate medication which proves dangerous in hypoglycemia and hyperglycemia.

A falsely elevated glucometer reading in severe hyperglycemia can result in insulin overdose, leading to life threating hypoglycemia. Clinicians should advice patients, whenever the readings are near the thresholds by glucometer; verify the results with centralized laboratory, which has the added advantage of quality control.

Approximately 91–97% of overall inaccuracies are due to operational factors. 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, hemolyzed sample.

ISO (International Organization for Standardization) recommends that total analytical error for glucometer to be within ± 15 mg/dl when glucose values are 100mg/dl[18] **CDC** (Centre for disease control) has determined an expected error of ± 20 mg/dl for blood glucose <100mg/dl.

Statistical analysis showed a significant difference with P value and Pearson's correlation value which was correlated with this study done by **Dahman, L.S.B, et al** (paired t-test $p < 0.001$, $r = 0.96$).[19]

CONCLUSION

Hence it has been concluded that there are certain gaps between the blood glucose estimation by glucometer and autoanalyzer but the laboratory results are much more accurate and reliable. The mean bias of +8.5 mg/dL and statistically significant difference ($p < 0.001$) indicate that the two methods are not perfectly interchangeable, particularly for diagnostic decision-making. Glucometers remain clinically acceptable for routine monitoring and point-of-care testing, especially when laboratory confirmation is impractical. The glucometer should meet certain criteria of accuracy as these devices may have certain inherent errors. The result obtained by these devices should be interpreted with caution and whenever possible need to be verified with laboratory analyzer to minimize the erroneous result.

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