RESEARCH ARTICLE

EVALUATION OF A NEW GLUCOMETER COMPARED TO A TRUSTED LAB METHOD: IMPROVING ACCURACY IN DIABETES MONITORING

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ABSTRACT

Objective: *Accurate blood glucose monitoring is vital for effective diabetes management, as it guides treatment decisions and helps prevent complications.*

Study design: *The aim of this study was to evaluate the accuracy and reliability of a new personal glucometer, MedSenso (MS) by comparing its glucose readings with those from the standard Cobas Pro laboratory analyzer.*

Place and duration of study: *The multicentered study was conducted at Islamabad Diagnostic Center Pakistan, from Nov 2024 to Mar 2025 after ethical approval.*

Patients and Methods: *We tested 200 venous blood samples from diabetic patients using both devices.*

Results: *The results demonstrated a strong correlation between MedSenso and Cobas Pro, with a Pearson correlation coefficient of r = 0.978. The Cobas Pro measured an average glucose level of 208.40 mg/dL, while MedSenso showed a slightly lower average of 198.06 mg/dL. The standard deviations were 90.27 mg/dL and 85.33 mg/dL respectively, indicating slightly more consistent readings from MedSenso. Bland–Altman analysis showed that the differences between devices were small and within clinically acceptable limits, suggesting that the variation is unlikely to impact routine patient care.*

Conclusion: *Current study suggest that MedSenso provides comparable glucose measurements with those of Cobas Pro and reliable tool for point-of-care monitoring in clinical and home settings.*

Keywords: *Blood Glucose Monitoring, Cobas Pro, Diabetes Mellitus, MedSenso Glucometer, Point-of-Care Testing, Venous Blood*

INTRODUCTION

Diabetes mellitus is rapidly becoming one of the most significant global health challenges. According to the Global Burden of Disease (GBD) Study 2021 published by the University of Washington in *The Lancet*, approximately 537 million adults aged 20 to 79 were living with diabetes worldwide in 2021. This number is projected to increase to 643 million by 2030 and reach as high as 784 million by 2045, highlighting a substantial and ongoing rise in diabetes prevalence globally.[1,2]

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Diabetes is not only characterized by elevated blood glucose levels but is also associated with serious long-term complications, including cardiovascular disease, nephropathy, retinopathy, neuropathy, and an increased risk of limb amputations. These complications pose a considerable burden not only on individuals affected but also on healthcare systems worldwide, increasing both the demand for care and economic costs.

In Pakistan, the situation is particularly concerning. Recent estimates suggest that over 26 million adults are living with diabetes, making Pakistan one of the countries with the highest diabetes prevalence in South Asia.[2,3] Factors such as urbanization, sedentary lifestyles, dietary changes, and genetic predisposition contribute to this growing epidemic. The healthcare

infrastructure faces significant challenges in providing widespread diabetes screening and management, especially in rural and underserved areas. This makes the availability of reliable, easy-to-use, and affordable glucose monitoring devices critically important to improve early diagnosis and ongoing management of diabetes in the country.[4,5]

Blood glucose levels are categorized to guide diagnosis and management. Normal fasting blood glucose is defined as less than 100 mg/dL (5.6 mmol/L). Prediabetes is identified when fasting glucose ranges between 100 and 125 mg/dL (5.6 to 6.9 mmol/L), indicating impaired glucose regulation and a higher risk for developing type 2 diabetes. Diabetes is diagnosed when fasting glucose levels are 126 mg/dL (7.0 mmol/L) or higher on two separate occasions or when random glucose exceeds 200 mg/dL (11.1 mmol/L) in the presence of symptoms.[3,6-8] Maintaining glucose levels within the normal range is essential to prevent complications and improve quality of life.[9]

The increasing development of new medical devices underscores the need for thorough validation studies to verify their clinical accuracy and reliability in real-world settings. Understanding the capabilities and limitations of such devices assists patients, clinicians, and healthcare systems in adopting technologies that improve diabetes care. The findings from this study offer valuable insight into the utility of the MedSenso glucometer as a potential tool to enhance diabetes monitoring, especially in resource-limited clinics or home environments where access to full laboratory facilities is restricted.[3,4,5,10] We anticipate that these results will encourage wider adoption of patient-friendly devices that facilitate more accurate and convenient blood glucose monitoring, ultimately contributing to better diabetes control and outcomes.[6,11]

For comparison, we used the *Cobas Pro analyzer* (Roche Diagnostics), a laboratory-grade glucose measurement system widely regarded as a gold standard in clinical chemistry. It requires venous blood samples and is primarily used in hospital and laboratory environments.[5,9] By comparing MedSenso to Cobas Pro, this study aimed to assess whether the new glucometer could provide reliable glucose readings close to those from a trusted laboratory instrument, thereby offering a practical alternative for everyday diabetes management. In this study, we evaluated the performance of the MedSenso glucometer, a newly developed point-of-care blood glucose monitoring device designed for use in both clinical and home settings.

MATERIALS AND METHODS

This was a cross-sectional study conducted between November 2024 and March 2025 at the Islamabad Diagnostic Center (IDC), Pakistan, which operates over 120 branches nationwide, following approval from the Institutional Ethics Review Committee (approval number: ERBIDC21202505-ERC). The study was conducted in collaboration with the International Center of Medical Sciences Research (ICMSR), Islamabad, and the Army Medical College, Rawalpindi.

Participant Selection

A total of 200 adult participants previously diagnosed with either type 1 or type 2 diabetes mellitus were enrolled using a convenient non-random sampling method. Eligibility criteria included individuals aged 18 years or older who provided written informed consent. Exclusion criteria included individuals with known hematological disorders, severe anemia, or those who had recently received blood transfusions, as these conditions could interfere with the accuracy of glucose readings.

Ethical Considerations

All participants were fully informed about the purpose, procedures, risks, and benefits of the study. Written informed consent was obtained from each participant before enrollment. The study protocol was reviewed and approved by the institutional ethics board, and strict confidentiality of personal data was maintained throughout.

Device Under Evaluation

The MedSenso utilizes electrochemical biosensor technology, where glucose oxidase catalyzes the oxidation of glucose, generating an electrical signal proportional to the glucose concentration. Key features of the device include a minimal sample volume (~0.5 µL), rapid testing time (~5 seconds), and portability, making it suitable for both clinical and home use.

Reference Standard

The Cobas Pro Analyzer (Roche Diagnostics) was used as the reference laboratory standard. This high-precision device employs enzymatic colorimetric methods and integrates automated internal quality control systems to ensure accurate plasma glucose measurements. It requires venous blood samples and is widely regarded as a gold standard in clinical diagnostics.

Sample Collection and Handling

Blood samples were drawn by trained medical personnel using aseptic techniques. Venous blood was collected in sodium fluoride-containing tubes, which preserve glucose stability. Each sample was labeled and stored in temperature-controlled containers until analysis to maintain sample integrity.

Measurement and Analysis Protocol

Each sample was tested using both the MedSenso glucometer and the Cobas Pro Analyzer. Devices were calibrated and operated strictly according to the manufacturers' instructions.[4,5] Quality control procedures were rigorously followed, including the use of certified control materials and routine recalibration of equipment. Additionally, a subset of samples was retested to ensure consistency and accuracy. Any discrepancies were analyzed and resolved through comparison and re-evaluation.

Quality Assurance Measures

To maintain data validity and reliability, comprehensive quality assurance protocols were implemented. Both devices underwent regular maintenance and performance verification, and any deviations were immediately addressed. All analytical procedures were conducted in a standardized clinical laboratory environment, ensuring adherence to best laboratory practices.

RESULTS

Overall, the results demonstrated a strong linear correlation between the MedSenso and Cobas Pro devices, with a Pearson correlation coefficient of 0.978, indicating that the two methods generally tracked glucose variations in parallel. The average glucose measured by Cobas Pro was 208.40 mg/dL, compared to 198.06 mg/dL by MedSenso, with respective standard deviations of 90.27 mg/dL and 85.33 mg/dL. These small differences suggest that, on average, MedSenso provides readings consistent with the laboratory standard and with slightly less variability.

However, closer examination revealed several individual samples with relatively large discrepancies between the two devices. Notably, samples 22, 153, 160, and 198 exhibited differences exceeding 20 mg/dL. For example, sample 22 showed a difference of 24 mg/dL (Cobas Pro: 240 mg/dL vs. MedSenso: 216 mg/dL), while sample 160 had a 27 mg/dL discrepancy (Cobas Pro: 185 mg/dL vs. MedSenso: 158 mg/dL). These outliers may be attributed to factors such as sample handling variability, hematocrit interference, or intrinsic device limitations under certain physiological conditions. Despite these occasional larger differences, the overall agreement remained within clinically acceptable limits for routine glucose monitoring.

To further clarify the distribution of differences, Table I categorizes all 200 samples by the absolute difference between devices into four groups: differences of $\geqslant$ 10 mg/dL, $\geqslant$ 15 mg/dL, and $\geqslant$ 20 mg/dL. Of the total samples, 36 (18%) showed a difference of 10 mg/dL or more, 15 (7.5%) had differences of 15 mg/dL or more, and only 6 (3%) exceeded a difference of 20 mg/dL. These findings indicate that large discrepancies are infrequent and that most readings fall well within an acceptable margin of error for everyday clinical use.

Table I: Number of samples by absolute glucose difference between MedSenso and Cobas Pro

Difference Range (mg/dL)	Number of Samples	Percentage of Total (%)
$\geqslant$10	36	18
$\geqslant$15	15	7.5
$\geqslant$20	6	3

In clinical practice, such minor differences are unlikely to alter therapeutic decisions, particularly when patients use the same device consistently for self-monitoring. Nonetheless, for cases where highly precise glucose values are critical, such as insulin dose adjustments in hospital settings, confirmation with a laboratory analyzer remains advisable.

DISCUSSION

Accurate blood glucose monitoring is a cornerstone of effective diabetes management, and the reliability of glucometers plays a crucial role in ensuring patient safety and optimal therapeutic outcomes. Numerous studies have evaluated the accuracy of various glucometers in comparison with laboratory-grade analyzers, consistently highlighting the variability in performance among commercially available devices. For instance, studies by Smith et al.[10] Zhang et al.[11], and Kumar and colleagues[12] demonstrated correlation coefficients ranging from 0.90 to 0.98 when comparing portable glucometers against standard lab systems, with many devices showing acceptable clinical accuracy but occasional significant discrepancies. Our findings with the MedSenso glucometer, which yielded a Pearson correlation coefficient of 0.978 compared to the Cobas Pro analyzer, align well with these published data,

confirming MedSenso's competitive performance in real-world clinical settings.

In contrast, some lower-cost glucometers on the market have been reported to produce less reliable results, particularly at extreme glucose concentrations or under conditions of altered hematocrit, which can lead to dangerous clinical consequences.[13,14] The high level of agreement observed in our study suggests that MedSenso offers accuracy on par with higher-end devices, making it a trustworthy choice for both patients and healthcare providers.

From an economic perspective, the affordability of glucose monitoring devices is a critical factor influencing accessibility and adherence, especially in low- and middle-income countries like Pakistan, where diabetes prevalence is rapidly rising.[15] The MedSenso glucometer is priced competitively, with an approximate upfront cost of $30 USD per device and a per-test strip cost of approximately $0.50 USD. This positions it favorably against many popular glucometers, whose prices range from $25 to $50 USD for the device and $0.60 to $1.20 USD per test strip.[16,17] By offering comparable accuracy at a lower cost per test, MedSenso may improve affordability and encourage more consistent glucose monitoring among diabetic patients.

Furthermore, the ease of use and quick result turnaround time provided by MedSenso enhances its suitability for both clinical and home settings, addressing a significant barrier in diabetes self-care adherence. While laboratory analyzers like the Cobas Pro remain the gold standard, their higher costs, need for trained personnel, and longer processing times limit their accessibility outside specialized centers.

As diabetes becomes more common worldwide, accurate and affordable monitoring tools are more important than ever. Our results showed that MedSenso's performance closely matched that of the lab analyzer, supporting the idea that effective monitoring doesn't have to be expensive or limited to labs. This is especially important in places with fewer resources. Although people may choose glucometers based on what's available in their country or what brand they trust, the need for accuracy is universal. The very high correlation seen in this study (0.978) shows that MedSenso is not just an option, it's a strong contender in the glucose monitoring space. It's accurate enough for use in a wide range of healthcare settings.[10,11,12]

Most importantly, this study shows that innovation can bring lab-level accuracy into more hands. MedSenso proves that precision doesn't have to stay in the lab, it can become part of everyday care at home or in the clinic.

CONCLUSION

These findings suggest that MedSenso provides glucose measurements comparable to those of a laboratory-grade analyzer. Given its ease of use and rapid results, MedSenso could be a dependable tool for point-of-care monitoring in clinics and home settings. However, laboratory confirmation is recommended when highly precise glucose values are critical for clinical decisions.

CONFLICT OF INTEREST:

None.

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