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Advancing Anemia Screening: Performance of the Aspen Hb Meter Compared to Standard Methods

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***Abstract:** Anemia, a global health concern with significant prevalence in low- and middle-income countries, poses serious challenges for women of reproductive age, particularly in resource-constrained environments. Early and accurate hemoglobin estimation is critical for timely intervention; however, traditional methods like the cyanmethemoglobin assay and automated hematology analyzers are impractical in decentralized settings. This study evaluates the performance of the Aspen Hb meter, a portable, spectrophotometry-based device, against the Serachem SC-60+ auto hematology analyzer. Hemoglobin levels from 1,280 adult females were analyzed, showing a strong correlation ($R^2 = 0.977$) and clinically acceptable agreement in Bland-Altman analysis. The Aspen Hb meter achieved a sensitivity of 98.14%, specificity of 95.80%, and accuracy of 97.57%, with minimal diagnostic errors. Its portability, rapid response, and cost-effectiveness highlight its utility in point-of-care diagnostics and public health programs. This device offers a scalable solution for improving anemia screening and management in low-resource settings, particularly in maternal health initiatives.*

***Keywords:** Aspen Hb Meter, Hb estimation, Sensitivity, Specificity, Accuracy*

I. INTRODUCTION

Anemia is a pervasive global health issue in developing regions like West Africa, South Asia, and Central Africa [1]. Recent data highlights its persistent prevalence among women of reproductive age in 82 low- and middle-income countries, leading to exemplifying gender health inequities [2]. In India, the prevalence is even higher, with nearly 57% of women aged 15–49 affected, according to recent NFHS data [3]. Anemia, marked by low hemoglobin levels, impairs oxygen support, energy efficiency, cognitive functions, and productivity [4]. Common in women of reproductive age, it is a major cause of maternal mortality, preterm delivery, and low birth weight, demanding urgent intervention [5].

Regular monitoring of hemoglobin levels is a cornerstone of anemia diagnosis and management. Early detection allows timely interventions, such as dietary modifications, supplementation, or addressing underlying health conditions [6]. For women of reproductive age, regular monitoring is especially critical, as it aids in preventing maternal anemia and its severe consequences during pregnancy. However, traditional hemoglobin estimation methods, such as cyanmethemoglobin and automated hematology analyzers, present several challenges. While accurate, these methods require well-equipped laboratory settings, trained personnel [7], and extended processing times, making them less accessible in low-resource environments [8]. Rural areas, primary healthcare centers, and community health initiatives often lack the infrastructure to support these standard methods, creating a significant barrier to anemia diagnosis and management. These challenges highlight the urgent need for portable, cost-effective, and rapid hemoglobin estimation technologies that can be easily deployed in diverse settings.

Portable, rapid, and accurate hemoglobin estimation devices are increasingly recognized as transformative tools in clinical practice [9]. These devices are particularly beneficial in decentralized healthcare systems, enabling point-of-care diagnostics that can facilitate timely decision-making. They are also invaluable in public health campaigns, community health programs, and during emergencies where quick assessments of hemoglobin levels are crucial. The development of innovative, spectrophotometry-based hemoglobin estimation devices has opened new avenues for bridging the gap in anemia diagnostics by offering a balance between precision, cost-effectiveness, and portability [10]. This research article presents a comprehensive comparison of a newly developed spectrophotometry-based hemoglobin estimation device, the Aspen Hb meter against standard methods in terms of accuracy, ease of use, portability, and cost efficiency [18]. The study evaluates the device's performance across clinical settings to ensure its reliability and robustness. Additionally, it discusses the potential applications of such a device in public health programs and its contribution to addressing the burden of anemia [21]. By exploring the strengths and limitations of the Aspen Hb meter, the research aims to highlight its utility in improving anemia screening and monitoring practices. This work contributes to the ongoing efforts to make anemia diagnostics more accessible and efficient, particularly in low-resource environments, ultimately aiding in the global fight against anemia and its associated health challenges.

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II. METHODS AND MATERIALS

A. Hemoglobin Measurement

The study included 1280 adult women (aged ≥15 years) conducted at the NABH-accredited Life Care Hospital, Sector 7, Karnal, Haryana, between April 2024 to November 2024. Hemoglobin levels were measured using two distinct methods: the Aspen Hb meter and the Serachem SC-60+ auto hematology analyzer. The Aspen Hb meter, developed by Aspen Laboratories Pvt. Ltd., Delhi, India, operates on the principle of spectrophotometry, where the Aspen Hb meter determines the Hemoglobin and calculates Hematocrit values together with Aspen Hemoglobin microcuvette. The Serachem SC-60+, an electrical impedance-based analyzer, is recognized for its precision and reliability, making it the standard reference in this study. For the Aspen Hb meter, blood was collected from either capillary or venous sources. Capillary samples were obtained by finger prick, discarding the first drop, and collecting approximately 10 µL of blood with a capillary transfer tube, which was applied to the micro cuvette preloaded in the device. For venous samples, fresh blood was collected via venipuncture, mixed thoroughly, and 10 µL was applied to the micro cuvette using a pipette or dropper. The meter displayed results within seconds, which were recorded. Venous blood samples from all participants were simultaneously analyzed using the Serachem SC-60+ auto hematology analyzer after thorough mixing. Hemoglobin levels were interpreted following WHO guidelines for reference ranges specific to age and sex [11].

B. Statistical Analysis

The data analysis was conducted using GraphPad Prism 8.0 software. Hemoglobin measurements from 1280 participants were obtained using the Aspen Hb meter and compared with results from the Serachem SC-60+ auto hematology analyzer. To evaluate the relationship between the two devices, linear regression analysis was performed, and the Pearson correlation coefficient was calculated. Additionally, the Bland-Altman plot was constructed to assess the differences between the measurement methods, with differences in hemoglobin values plotted against their mean [12]. Method bias and limits of agreement were determined at a 95% confidence interval. The performance of the Aspen Hb meter was evaluated against the Serachem SC-60+, which served as the standard reference, in terms of accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). These parameters were calculated using the following formulas:

Accuracy = [((True Positives + True Negatives) / (True Positives + True Negatives + False Positives + False Negatives)) × 100]

Sensitivity = [(True Positives / (True Positives + False Negatives)) × 100]

Specificity = [(True Negatives / (True Negatives + False Positives)) × 100]

Positive Predictive Value (PPV) = [(True Positives / (True Positives + False Positives)) × 100]

Negative Predictive Value (NPV) = [(True Negatives / (True Negatives + False Negatives)) × 100]

Positive Likelihood Ratio (LR+) = Sensitivity / (100 – Specificity)

Negative Likelihood Ratio (LR-) = (100 – Sensitivity) / Specificity

Disease Prevalence = [((True Positive + False Negative) / Total Sample) × 100]

This analysis allowed for a comprehensive assessment of the Aspen Hb meter's performance relative to the standard hematology analyzer, considering diagnostic accuracy and reliability.

III. RESULTS AND DISCUSSION

The study included a total of 1,280 adult females from Haryana, India, with participants categorized into seven age groups to ensure a diverse sample distribution (Table 1).

Table 1: Distribution of Samples Based on Age

Age	Number of Samples
<20	37
21-30	374
31-40	347
41-50	186
51-60	113
61-70	144
>71	79
Total	1280

The age group <20 years comprised 37 individuals (2.9%), while 374 participants (29.2%) were aged 21–30 years. A significant proportion, 347 individuals (27.1%), belonged to the 31–40 years age group, followed by 186 (14.5%) in the 41–50 years range. Additionally, 113 participants (8.8%) were aged 51–60 years, 144 (11.3%) were between 61–70 years, and 79 individuals (6.2%) were aged >71 years. This stratified distribution ensures representation across a wide age spectrum, enabling a comprehensive evaluation of the hemoglobin estimation device's performance across varying physiological and clinical contexts.

The Hb levels obtained were in a range of 5.2 g/dL to 15.7 g/dL for Aspen Hb meter with a mean of 10.71 ± 1.61 g/dL and 10.77 ± 1.65 g/dL for venous and capillary samples, respectively, as compared to Serachem SC-60+ Automated hemato-analyzer which showed 5.0 – 15.1 g/dL concentration range with a mean of 10.76 ± 1.61 g/dL (Table 2).

Table 2: Hemoglobin Values of the Study Population

Test	Sample Type	Hb (g/dL) (Mean ± SD)	Range (g/dL)
Aspen Hb Meter	Venous (n=672)	10.71 ± 1.61	5.9 – 15.5
	Capillary (n=608)	10.77 ± 1.65	5.2 – 15.7
Searchem SC-60+Automated hematology Analyzer	Venous (1280)	10.76 ± 1.61	5.0 – 15.1

Sensitivity analysis revealed that the Aspen Hb meter achieved a sensitivity of 98.14% (95% CI: 97.12–98.91%), indicating a high ability to correctly identify individuals with anemia (Hb levels <12.0 g/dL, according to WHO) [11]. Specificity was determined to be 95.80% (95% CI: 92.75–97.58%), showing reliable discrimination of non-

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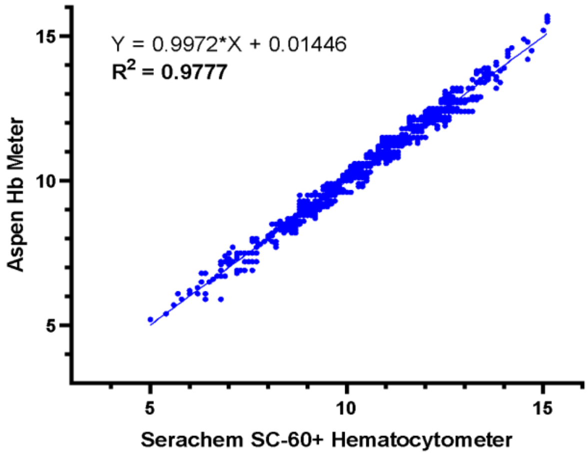
anemic individuals (Table 3). These metrics, combined with a positive predictive value (PPV) of 98.65% (95% CI: 97.63–99.14%) and a negative predictive value (NPV) of 94.28% (95% CI: 91.46–96.40%), underscore the device's robust performance in clinical settings. The disease prevalence in this cohort was 75.78% (95% CI: 73.03–77.78%), consistent with the high prevalence of anemia reported in similar demographic studies in India. The accuracy of the Aspen Hb meter was measured at 97.57% (95% CI: 96.54–98.31%), with a positive likelihood ratio of 23.40 (95% CI: 13.40–37.33) and a negative likelihood ratio of 0.019 (95% CI: 0.01–0.03), emphasizing its diagnostic precision and utility in detecting true positive and negative cases (Table 3).

Table 3: Statistical Parameters to Evaluate the Performance of Aspen Hb Meter

Parameters	Total	Venous	Capillary
Sensitivity	98.14%	98.63%	97.60%
Specificity	95.80%	96.27%	95.30%
Accuracy	97.57%	98.06%	97.03%
PPV	98.65%	98.82%	98.46%
NPV	94.28%	95.67%	92.81%
Positive likelihood ratio	23.40	26.46	20.77
Negative likelihood ratio	0.019	0.014	0.025
Disease Prevalence	75.78%	76.04%	75.49%

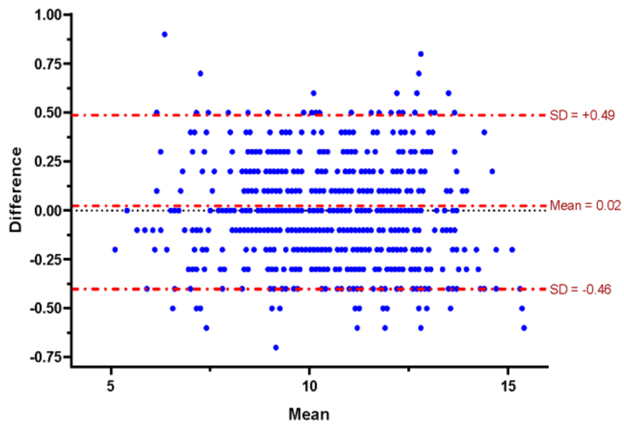
The linear regression analysis between hemoglobin measurements obtained from the Aspen Hb meter and the Serachem SC-60+ auto hematology analyzer demonstrated a strong correlation, with an R^2 value of 0.977 (Fig. 1).



[Fig.1: Linear Regression Analysis Between Aspen Hb Meter and Searchem SC-60+ Automated Hematology Analyzer]

This high coefficient of determination indicates that the measurements from the two devices are closely aligned, with minimal variance. The regression line's slope was nearly one, reflecting the Aspen Hb meter's ability to provide results comparable to the standard reference method. Notably, 257 samples exhibited no difference in hemoglobin values between the two methods, further emphasizing the consistency of the Aspen Hb meter. The close agreement highlights the potential of the spectrophotometry-based device as a viable alternative for hemoglobin estimation in diverse clinical settings, particularly where access to advanced hematology analyzers is limited.

The Bland-Altman analysis provided further validation by assessing the agreement between the two methods. The plot revealed a mean difference close to zero, with the majority of data points falling within the 95% limits of agreement, which ranged from -0.7 g/dL to 0.9 g/dL (Fig. 2).



[Fig.2: Bland & Altman Plot with Differences in Hb Level Estimation Obtained from Aspen Hb Meter and Serachem SC-60+ Automated Hematology Analyzer Plotted Against the Mean of the Values]

These limits represent the maximum observed differences between the Aspen Hb meter and the hematology analyzer, signifying a clinically acceptable margin. The plot also showed no systematic bias across the range of hemoglobin concentrations, indicating the uniform performance of the Aspen Hb meter irrespective of the hemoglobin level [19]. This level of agreement is comparable to findings in prior studies evaluating similar devices, such as those by Gupta et al. (2008), where limits of agreement remained within ±1 g/dL [13]. These findings bolster confidence in the reliability and accuracy of the Aspen Hb meter for routine hemoglobin estimation in both clinical and resource-constrained environments [20].

Comparison with prior literature highlights the Aspen Hb meter's competitive performance. Traditional hemoglobin estimation methods, such as the cyanmethemoglobin method, are known for their accuracy but are time-intensive and require laboratory infrastructure, limiting their applicability in resource-constrained environments. Automated analyzers like the Serachem SC-60+ are highly reliable but are expensive and dependent on advanced laboratory settings, making them less accessible in rural areas and field settings [14]. In contrast, other portable devices, such as the HemoCue system, have shown comparable accuracy but sometimes fall short in specificity or sensitivity [15]. For instance, a recent study by Neogi et al. (2022) reported a sensitivity of 96.5% and specificity of 92.3% for the HemoCue system, slightly lower than the values observed for the Aspen Hb meter in this study [16]. This suggests that the Aspen Hb meter may offer a more balanced and robust diagnostic tool for anemia screening, particularly in field settings and rural areas where advanced laboratory equipment is limited. A key strength of the Aspen Hb meter lies in its adaptability for point-of-care use, with capillary and venous sampling options providing flexibility. The device's ability to generate rapid results without requiring extensive technical expertise or infrastructure makes it a promising tool for anemia screening programs, particularly in regions where high anemia prevalence necessitates widespread and efficient diagnostic coverage. False positives and false negatives were analyzed to assess the device's limitations further. The false positive rate was 4.39%, and the false negative rate was 1.83%, indicating minimal diagnostic errors. These findings are essential in clinical decision-making, as a low false negative rate ensures fewer anemic individuals are missed, while a low false positive rate reduces unnecessary treatment.

Moreover, the portability and ease of use of the Aspen Hb meter make it a valuable addition to public health initiatives, particularly in areas where healthcare infrastructure is limited. Programs targeting maternal health, for instance, could benefit significantly from its deployment, as timely anemia detection is critical in reducing maternal morbidity and mortality. A comparison with optical methods such as non-invasive devices highlights the Aspen Hb meter's superiority in accuracy and reliability. While non-invasive devices eliminate the need for blood collection, studies (e.g., Avcioglu et al., 2018) indicate that their sensitivity and specificity often lag behind traditional or semi-traditional devices, underscoring the need for a balance between innovation and diagnostic reliability [17].

IV. CONCLUSION

This study underscores the effectiveness of the Aspen Hb meter as a portable, cost-efficient, and reliable alternative for hemoglobin estimation in clinical and resource-limited settings. With a high sensitivity of 98.17% and specificity of 95.61%, the device demonstrates robust diagnostic performance, closely aligning with the results from the standard Serachem SC-60+ auto hematology analyzer. The strong correlation ($R^2 = 0.977$) between the two methods and the clinically acceptable agreement observed in the Bland-Altman analysis further validate its accuracy and reliability. The device’s rapid response time and dual capability for capillary and venous blood sampling enhance its practical utility, making it especially valuable for point-of-care diagnostics and anemia screening programs. Notably, the Aspen Hb meter outperformed many existing portable devices, such as the HemoCue system, in terms of specificity and overall accuracy, while offering comparable sensitivity. The low rates of false positives (4.39%) and false negatives (1.83%) minimize diagnostic errors, ensuring that the majority of anemic cases are correctly identified while reducing unnecessary interventions. These strengths make the Aspen Hb meter a promising tool for public health initiatives, particularly in areas with limited access to advanced laboratory infrastructure. Its potential for widespread implementation in maternal health programs is particularly noteworthy, given the critical importance of early anemia detection and management in reducing maternal morbidity and mortality.

This research contributes to the ongoing efforts to bridge the gap in anemia diagnostics, particularly in low-resource environments. By offering a balance between precision, portability, and affordability, the Aspen Hb meter addresses key challenges associated with traditional and automated hematology analyzers. Future studies should explore its application in other demographic groups and geographies to assess its scalability and impact
on global anemia management.

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DECLARATION STATEMENT

After aggregating input from all authors, I must verify the accuracy of the following information as the article's author.

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Dr. Ashish Nasa is a medical professional currently pursuing a postgraduate residency in Radio-diagnosis at Al-Ameen Medical College and Hospital, Vijaypur. He earned his MBBS degree from Subharti Medical College, Meerut, where he laid a strong academic and clinical foundation. Prior to his residency, Dr. Nasa worked as a Junior Resident at BPS Medical College, Khanpur, Haryana, gaining valuable experience in patient care and critical care medicine. With expertise in advanced radiological practices and medical diagnostics, his rigorous training and research reflect a commitment to excellence. Dr. Nasa aspires to leverage his diagnostic proficiency and research insights to advance radiology and patient outcomes.

Pankaj Mutreja is currently serving as the laboratory in charge at Life Care Hospital, an NABH-accredited healthcare facility located in Sector 7, Karnal, Haryana. With extensive expertise in essential pathological laboratory techniques, he is proficient in performing hematological and immunological assays, enzyme-linked immunosorbent assays (ELISA), complete blood count (CBC) tests, and other diagnostic procedures critical for patient care. Pankaj holds a Bachelor of Science degree in Medical Laboratory Technology (B.Sc. MLT), equipping him with a strong foundation in medical diagnostics. His dedication to precision and efficiency ensures the delivery of reliable results, contributing significantly to the hospital's high standards of diagnostic services.

Rohtash Bhardwaj is currently employed as a laboratory technician at Life Care Hospital, an NABH-accredited institution located in Sector 7, Karnal, Haryana. He brings valuable expertise in a range of diagnostic laboratory procedures, with a particular focus on serological, biochemical, and hematological testing. Rohtash is proficient in conducting complete blood count (CBC) analyses, enzyme-linked immunosorbent assays (ELISA), urine biochemistry tests, and other critical diagnostic tests. His hands-on experience and commitment to accuracy ensure the delivery of precise and reliable test results, which play a vital role in patient care and clinical decision-making. Rohtash's skills contribute to the hospital's reputation for quality healthcare services.

Dr. Pankaj K. Tyagi is a Professor and Dean of Research at the Noida Institute of Engineering and Technology, Gautam Buddha Nagar, Uttar Pradesh. He holds a Ph.D. in Drosophila Biology from Maharishi Dayanand University, Haryana, and has over 17 years of research experience spanning Biotechnology, Nanobiotechnology, and Drosophila Biology. Dr. Tyagi's extensive research contributions include numerous peer-reviewed publications. His research reflects a multidisciplinary approach to advancing science and addressing real-world challenges, earning him recognition in esteemed journals like Letters in Organic Chemistry and Synthetic Communications. Dr. Tyagi has also made significant strides in nanotechnology, including biosynthesis and evaluation of antibacterial and antioxidant silver nanoparticles, further cementing his reputation as a leader in the field.