International Journal of Advanced Pharmaceutical Sciences and Research (IJAPSR)
ISSN: 2582-7618 (Online), Volume-2 Issue-2, February 2022

Hemoglobin Levels Estimation using Aspen HB Meter

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Abstract: ***Hemoglobin (Hb) is an iron-containing metalloprotein present in red blood cells that carries and transports oxygen from the lungs to the tissues. Hb is an essential clinical parameter to evaluate since its insufficiency is recognised to be the major cause of anaemia. In general, the Hb measuring procedure necessitates a complex and costly laboratory setup staffed by highly experienced specialists. In underdeveloped nations, especially in rural and distant places, such a complex setup and knowledge is difficult to construct. As a result, a quick and portable Hb diagnostic test is urgently needed to improve test accessibility in these places, with the added benefit of offering point-of-care diagnostic tests (POCT) at the patient's door and in the field for mass screening at lower costs. Aspen Hb meter, developed by Aspen Laboratories Pvt. Ltd and available on the market, is one such instrument. Aspen Hb meter has 94 % accuracy, 93.3 % sensitivity and 94.8% specificity when compared to an automated haematology analyzer (Serachem SC-60+). As a result, the Aspen Hb meter was shown to be an acceptable POCT device for Hb monitoring in clinical and field settings.***

Keywords**: *Aspen Hb meter, Hb Monitoring, Point-Of-Care Diagnostic Tests, Sensitivity, Specificity.***

I. INTRODUCTION

Anemia is defined as a lack of oxygen delivery to tissues due to a decrease in the amount of red blood cells or haemoglobin (Hb) in the blood [1]. It causes symptoms such as weakness, weariness, chest discomfort, and shortness of breath, which leads to a weakened immune system, increased illness susceptibility, stunted growth, and aberrant neurological development [2–3]. It can exacerbate defective cognitive development in children, leading to severe impairment and dementia in adults, resulting in a variety of mental health issues and affecting the country's socio-economic progress [4-7]. Approximately, 22.8% (95% CI: 22.6-23.1) population, including 29.9% (95% CI: 26.6-32.5) women and 39.8% (95% CI: 36.0-43.8) children, is affected by anemia worldwide [8]. Though chronic diseases and genetic disorders can cause anaemia, the leading underlying cause is a nutritional deficiency in iron, vitamin B12, and folic acid, which explains its high prevalence in low-income countries such as Africa, Southeast Asia, and the Eastern Mediterranean, with women and children being particularly vulnerable [9, 10]. Most of the countries are trying to address this problem and are designing strategies to combat the same.

In order to combat anemia, its detection is of utmost priority. The commonly used diagnostic indicator for anemia is Hb [11, 12]. Hb is a globular protein, present in erythrocytes, which binds to oxygen and transports it to different tissues. The usual method of Hb measurement employs large, complicated and sophisticated instruments. Although these instruments are reliable, they often require proper lab infrastructure, routine maintenance, continuous electricity supply, trained personnel, controlled environment etc. for their proper functioning which makes it difficult to establish these equipments in rural and remote areas [13, 14]. Pregnant women require regular and consistent Hb screening and thus, they suffer more due to the lack of testing facility resulting in higher mortality. Therefore, a portable rapid test is required that can be easily employed in field settings with doorstep examination. In addition to promoting Hb analysis at mass level, such a test will also provide point-of-care diagnostics for healthcare workers to give proper therapeutic administration. In the present study, we have estimated Hb levels by portable rapid Aspen Hb meter available in the market and compared the same with Serachem SC-60+ automated hematology analyzer for evaluating accuracy, sensitivity, specificity and other statistical parameters of Aspen Hb meter.

II. MATERIALS & METHODS

A total of 947 participants were randomly taken for the study which included 475 men (age ≥ 15 years) and 472 women (age ≥ 15 years). The study was conducted at NABH accredited Life Care Hospital based at Karnal, Haryana, India from the period of October 2021 to November 2021. Aspen Hb meter is a rapid and portable diagnostic test manufactured by Aspen Laboratories Pvt. Ltd., Delhi, India. It was assessed for its performance by comparison with automated hematology analyzer- Serachem SC-60+. For Hb measurement on Aspen Hb meter, test strip was inserted into the meter and blood sample was collected from either capillary or vein. For capillary blood extraction, subject's finger was wiped with an alcohol swab and pricked using a lancet. The first drop of blood was wiped and the second drop was collected using a capillary tube. For drawing venous blood, a tourniquet was tied to subject's upper arm and the selected puncture site was cleaned with an alcohol swab.

Manuscript received on 07 January 2022 | Revised Manuscript received on 28 January 2022 | Manuscript Accepted on 15 February 2022 | Manuscript published on 28 February 2022.

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A syringe needle was inserted at an angle of 15-30 degrees into the vein and the blood was extracted. Venous blood sample was mixed and 10 µl blood was placed onto the specimen application area on the test strip using a capillary tube, or pipette. Reading for hemoglobin level was obtained within few seconds and was recorded. Serachem SC-60+ automated hematology analyzer is known to give reliable and accurate results and therefore, was selected for this study as a reference method for Hb measurement using Aspen Hb meter. For analysis on Serachem SC-60+ automated hematology analyzer, venous blood was extracted from each participant and mixed thoroughly before analysis. The reference Hb values as were followed as per WHO guidelines (Table 1) [15].

Table I: Hemoglobin Reference Value for Non-Anemic and Anemia Individuals based on Gender

Gender	Hemoglobin Levels	
	Non-Anemia	Anemia
Women (≥15 years)	≥12 g/dl	≤80-11.9 g/dl
Men (≥15 years)	≥13 g/dl	≤80-12.9 g/dl

Statistical Analysis:

Microsoft Excel was used for data analysis. The association between the Aspen Hb meter and the Serachem SC-60+ automated hematology analyzer was evaluated using linear regression analysis. The Pearson correlation coefficient was used to determine the relationship's strength. To compare the Aspen Hb meter with the Serachem SC-60+ automated haematology analyzer, a Bland and Altman plot was created, with the mean of the values obtained from the two approaches represented on the X-axis and the difference of the values plotted on the Y-axis. The bounds of agreement were calculated using a 95% confidence range and method bias was evaluated. Table 2 shows the true positive, true negative, false positive, and false negative predictions.

Table II: Parameters to classify True Positive, True Negative, False Positive and False Negative

	True Positive	True Negative	False Positive	False Negative
Serachem SC-60+ Automated Hematology Analyzer	Anemic	Non-Anemic	Non-Anemic	Anemic
Aspen Hb Meter	Anemic	Non-Anemic	Anemic	Non-Anemic

III. RESULTS AND DISCUSSION

Anemia is a global health concern affecting approximately 1.62 billion people worldwide [16]. Several health policies have been designed for prevention and control of anemia with emphasis on adequate dietary intake. The key aspect of these policies is to diagnose the condition before and after the strategic measures have been implemented. Anemia detection is usually conducted by measuring Hb levels. Levels of Hb in blood are used as indicator to assess the severity of anemia to facilitate appropriate therapeutic interventions. Blood Hb levels are clinically measured using automated hematology analyzers which are based on techniques such as impedance, light scatter, fluorescence scatter etc. to generate reliable and accurate results [17, 18]. These analyzers are complex instruments that require skilled personnel, proper lab setup, detailed maintenance and repetitive replenishment of reagents. Therefore, installation and establishment of these instruments is difficult in rural and remote areas causing Hb measurement challenging in such regions. This problem can be addressed by a portable Hb measuring device which could be applicable in field settings. Aspen Hb meter manufactured by Aspen Laboratories Pvt. Ltd. is one such portable and rapid test that employs colorimetric conversion of Hb into methemoglobin and quantitative Hb determination by reflectance photometry. Aspen Hb meter was assessed for its performance and compared with Serachem SC-60+ automated hematology analyzer, well known for its accuracy, specificity & sensitivity. Serachem SC-60+ automated hematology analyzer is based on Coulter principle where a cell increases impedance when it passes through an aperture with free flow of current. Thus, the study was conducted to assess the performance of Aspen Hb meter by keeping Serachem SC-60+ automated hematology analyzer as standard reference. To compare the relationship between the results obtained by Aspen Hb meter and Serachem SC-60+ automated hematology analyzer, linear regression analysis was performed. The high R2 value of 0.99 indicates a negligible variation in the Hb values obtained by both the instruments (Fig 1). Pearson correlation coefficient of 0.995 (p-value<0.00001) demonstrates a strong positive linear relationship between the two instruments.

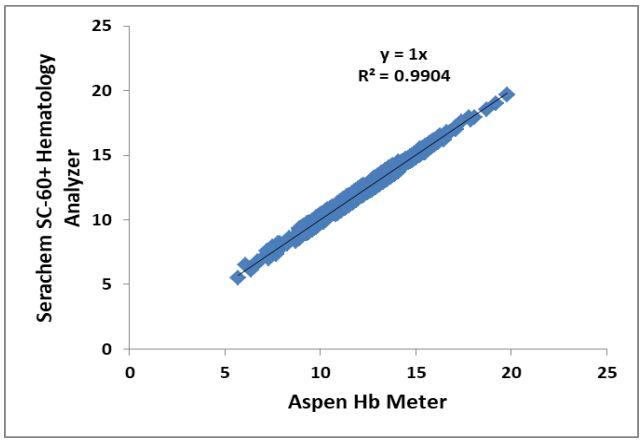

Fig 1: Linear Regression analysis between Aspen Hb meter and Serachem SC-60+ Automated Hematology Analyzer

Bland and Altman plot was also drawn to explore the agreement between Aspen Hb meter and Serachem SC-60+ automated hematology analyzer. Uniform distribution of data points across the mean difference without concentration based clustering of values suggests absence of bias by Aspen Hb meter over Serachem SC-60+ automated hematology analyzer.

Method bias of 0.001g/dl with 0.411g/dl and -0.409g/dl as upper and lower limits of agreement respectively was obtained representing good agreement between the two measurement methods (Fig 2).

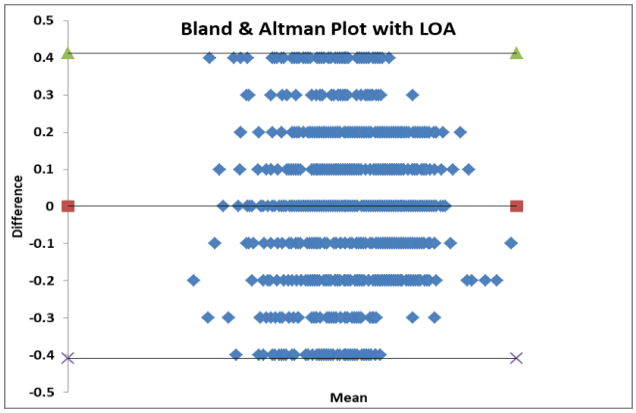

Fig 2: Bland and Altman Plot with differences of Hb levels obtained from Aspen Hb meter and Serachem SC-60+ automated Hematology Analyzer plotted against mean of the values.

Statistical parameters like accuracy, sensitivity, specificity were also evaluated to gauge the performance of Aspen Hb meter against Serachem SC-60+ automated hematology analyzer. In comparison to Serachem SC-60+ automated hematology analyzer, Aspen Hb meter exhibited 94% accuracy, 93.3% sensitivity and 94.8% specificity (Table 3).

Table III: Statistical Parameters to evaluate the performance of Aspen Hb Meter

	Total	Venous	Capillary
Accuracy	94%	95.20%	92%
Sensitivity	93.30%	93.70%	92.80%
Positive Predictive Value	92.60%	92.80%	92%
Negative Predictive Value	95.30%	96.20%	93.50%
Specificity	94.80%	95.70%	93%

In conclusion, performance of Aspen Hb meter was evaluated in comparison to Serachem SC-60+ automated hematology analyzer for Hb measurement. Regression analysis with R^2 value of 0.99 and correlation coefficient of 0.995 (p-value<0.00001) demonstrated strong relationship between the two measurement methods. Bland and Altman plot with method bias of 0.001g/dl with 0.411g/dl as upper limit of agreement and -0.409g/dl as lower limit of agreement indicated good agreement between the data obtained from Aspen Hb meter and Serachem SC-60+ automated hematology analyzer. Accuracy, sensitivity, specificity, positive predictive value and negative predictive value of 94%, 93.3%, 94.8%, 92.6% and 98.3% respectively was achieved with Aspen Hb meter. The results, thus, substantiate the applicability of Aspen Hb meter for use in clinical as well as field settings as point-of-care device.

IV. CONCLUSION

Anemia is one of major problem faced by developing & underdeveloped nations with majority cases found in pregnant women & children under 5. Hb is an essential clinical marker for accessing anemia. In general, the Hb measuring procedure necessitates a expensive, complicated & complex equipment with highly trained specialists, which is difficult in field and rural settings.

As a result, a quick and portable Hb diagnostic point of care test (POCT) is the need of the hour for mass screening at lower costs. Aspen Hb meter, developed by Aspen Laboratories Pvt. Ltd and available on the market, is one such instrument. Aspen Hb meter has 94 % accuracy, 93.3 % sensitivity and 94.8% specificity with Pearson correlation coefficient of 0.995 (p-value<0.00001) when compared to an automated haematology analyzer (Serachem SC-60+). As a result, the Aspen Hb meter was shown to be an acceptable POCT device for Hb monitoring in clinical and field settings.

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