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Assessing Diagnostic Accuracy of HbChek- Innovative Indigenous Hemoglobinometer

Wahid Ali, Aliya Rizvi, Wamique Khan, Neha Srivastava, Zoya Shakir, Paurabhi Singh

Clinical Pathology, Department of Pathology, King George's Medical College, Lucknow, UP, India

ABSTRACT

The aim of this study was to evaluate the performance of the portable Hemoglobinometer "HbChek" by comparing its performance against automated Three-part hematology analyzer, Medonic M20. Total 731 venous blood samples were subjected through their total hemoglobin evaluation. Each sample was run only once on reference device and HbChek. The two set of values were comparatively analyzed. The repeatability of the performance of HbChek was also evaluated against Medonic M20 values. The scatter plot of HbChek values and Medonic M20 values showed linear distribution with regression correlations r=0.99. The intraclass correlation (ICC) between the two set of values was found to be 0.9952 with 95% confidence intervals (CI) ranging between 0.9945 and 0.9959. The mean difference in Bland–Altman plots of HbChek values against the Medonic M20 values was found to be -0.08 g/dL, with limits of agreement between 0.60 g/dL and -0.75 g/dL. Coefficient of Variation was found to be 2.8% (SD/Mean=0.35/12.4). Sensitivity & Specificity was found at 93.2 % & 98.6% respectively. These results suggest a strong positive correlation with laboratory machines differences less than 0.8 g/dL. In addition, high sensitivity &high specificity value with easiness of use can make HbChek appropriate technology for public health systems like Sub-Centers & PHCs.

Keywords: Hemoglobinometer, Coefficient of Variation, Sensitivity & Specificity

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***Address for Correspondence:**

Prof. Wahid Ali, Clinical Pathology Laboratory, Department of Pathology, King George's Medical College, Lucknow, UP. 226003

INTRODUCTION

The burden of anemia remains unacceptably high in Indian population. Prevalence of anemia in infants and children (6–59 months) is 68% and in pregnant woman is 59%[1]. There are many life-threatening consequences of anemia, cognitive impairment;decreased physical capacity and reduced immunity are commonly associated with iron-deficiency anemia[2]. Hence timely and accurate diagnosis is imperative to prevent its effect [3]. The blood hemoglobin levels can be measured using various methods such as cyanmethemoglobin, use of copper II sulfate, automated hematology analyzers and point-of-care (POC) devices[4-8]. Out of these methods automated analyzers are considered as gold standard. However, automated analyzer cannot be used in rural area especially where there is scarcity of electricity. Also these are expensive analyzer, required daily maintenance and well trained skilled operator. Considering these facts automated analyzers can be only used in urban areas where required infrastructure and skilled man power is available.

Hence methods those are low cost, do not required electricity, daily maintenance and highly skilled human resources such as cyanmethemoglobin, gravimetric copper II sulfate and color code hemoglobin estimation are commonly used in area with scarcity of resources [5, 7, 9, 10]. However these methods are not completely reliable due to lack of accuracy and high observer error[11]. This clearly warrants the need of user friendly, economical, sensitive, robust and accurate device to test the Hemoglobin in such rural areas with scarcity of resources [7, 8]. Point of care devices can play a vital role due to its portability, accuracy, low cost maintenance, simple operation and ability to work on batteries.

HbCheck® Hemoglobinometer is a Point of care diagnostic device that utilizes fresh capillarywhole blood samples or venous blood sample to measure hemoglobin accurately developed & Manufactured by Biosense technologies Pvt Ltd, India. It is based on the principle of photometry (Spectrometry). To assess the accuracy of HbCheck® vs.Lab gold standard automatic hematology analyzer "Medonic M20" this study was designed and conducted in Dept. of Pathology at King George Medical University, Lucknow, Uttar Pradesh, India.

MATERIAL AND METHODS

Medonic M20 an automated Three-part hematology analyzer were used as a reference for examining the performance of HbChek. Medonic M20 works on photometric principal to measure the Hemoglobin. The instrument has been proved to provide accurate and reliable results of WBC, RBC, MCV,

Platelet and Hemoglobin. As a standard practice the quality control of the Medonic M20 was performed every day during this study.

HbChek meter consists of an analyzer together with test consumables. The test consumables serve both as a pipette and measuring part. The measurement is taken by multiple wavelengths including isosbestic point of Hemoglobin (Oxy-Deoxy Hb).

In this study 731 samples submitted to the Department of Pathology, Kings George Medical University, Lucknow, Uttar Pradesh, India for Hematology analysis was selected randomly for the study. The analysis performed on real time basis. The samples were run by two trained lab technicians independently once on Medonic M20 hematology analyzer and once HbChek Hemoglobinometer simultaneously. Each sample was identified by a laboratory specific sample id which has no correlation with Hemoglobin value. The results obtained were recorded on case report form along with sample id/ reference number separately by the concern technician. At no point of time the results were exchanged between two technicians.

Bland and Altman analysis, ICC analysis, regression analysis, and correlation analysis were carried between HbChek values and Medonic values. Repeatability of performance of HbChek was also studied by studying its CV.

RESULTS AND DISCUSSION

Subject Demographics and Hemoglobin Range:

In this study total 731 (Female 291 and Male 440) samples were studied. The subjects demographics is given in the below Table 1 and Table 2.

Table 1. Demographics and Hemoglobin Range (Female, n= 291)

Completed Age	Number of subjects	Hemoglobin Range g/dl
1 to 4 yrs.	16	4.5 to 14
5 to 11 yrs.	15	10.3 to 12.8
12 to 14 yrs.	11	3.6 to 14.7
15 yrs. & above	249	2.7 to 15.9

Table 2. Demographics and Hemoglobin Range (Male, n=440)

Completed Age	Number of subjects	Hemoglobin Range g/dl
1 to 4 yrs.	18	4.8 to 14.4
5 to 11 yrs.	38	8.8 to 15.6
12 to 14 yrs.	12	9.3 to 14.6
15 yrs. & above	372	3 - 19.1

Table 3. Hemoglobin thresholds used to define anaemia in this study as per WHO

Age or gender group	Haemoglobin threshold g/dl
Children (0.50-4.00 yrs.)	11.00
Children (5.00-11.99 yrs.)	11.50
Children (12.00-14.99 yrs.)	12.00
Non-pregnant women (> 15 yrs.)	12.00
Male (> 15 yrs.)	13.00

Descriptive Statistics:

Data were entered into the Microsoft excel. Agreement between the test methods was assessed using the Bland and Altman method [12, 13], where the mean, standard deviation and limit of agreement of paired results were calculated and accuracy was estimated by calculating bias values along with intraclass correlation coefficients (ICCs). The ICCs were interpreted as follows: <0: poor; 0.01–0.20: slight agreement; 0.21–0.40: fair agreement; 0.41–0.60: moderate agreement; 0.61–0.80: substantial agreement and 0.81–1.00: almost perfect agreement13. Performance evaluation was based on measurement of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV). Hemoglobin thresholds used to define anaemia in this study as per WHO is tabulated in Table 3.

Diagnostic Performance of HbChek® and Medonic M20:

The average measure of accuracy of the two assays as measured by the ICC was 0.9952 with 95% confidence interval level ranging from 0.9945 to 0.9959 which indicates an almost perfect correlation between the two assays. Anemia defined by Medonic M20 results in Two by Two in Table 4 and Statistical Parameters in Table 5.

In Addition, 2X2 table Analysis was performed to calculate

Sensitivity : True Positive/ (True positive + False negative)

Specificity : True Negative/ (True negative + False positive)

Positive Predictive Value (PPV) = True Positive / (True Positive + False positive)

Negative Predictive Value (NPV) = True negative/ (True Negative + False Negative)

Table 4. Two by Two table

Anemia defined by M20 results			
		Present (n)	Absent (n)
HbChek Test	Positive	289 (True +ve)	06 (False +ve)
	Negative	21 (False -ve)	415 (True -ve)

Table 5. Statistical Parameters

Parameters	Values
Mean Bias	-0.08
Standard Deviation	0.35
Mean Hemoglobin	12.40
Upper LOA	0.60
Lower LOA	-0.75
Sensitivity	93.2%
Specificity	98.6%
Positive Predictive Value (PPV)	98.0%
Negative Predictive Value (NPV)	95.2%
CV (SD/Mean)	2.79%

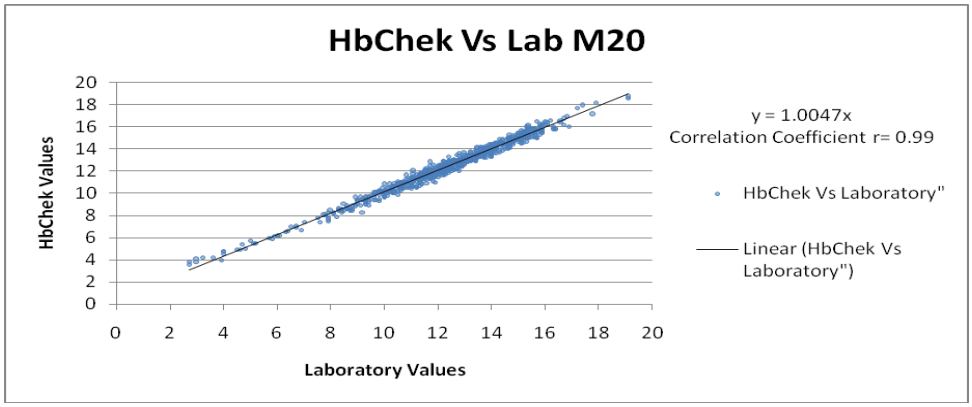

Figure1. Correlation Graph between HbChek & Lab M20 with equation & r Value.

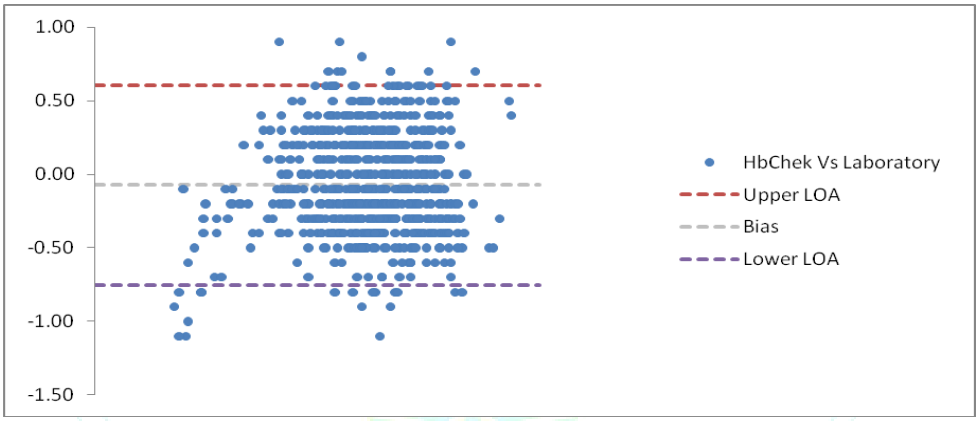

Figure 2. Bland Altman Plot with Upper & Lower limits +/-2SD (95% reading).

Correlation studies suggested good agreement between HbChek values and Medonic M20 values (Figure 1). Intraclass correlation coefficient was found as 0.9952, with 95% confidence interval as (0.9945, 0.9959). Regression coefficient through origin was observed to be 0.99. Bland and Altman plot analysis 95% limits of agreement was found to be between 0.60 g/dL and - 0.75 g/dL, with mean difference (bias) as -0.08. Statistical analysis suggested good precision (repeatability) in the results of HbChek. A low mean CV of 2.79% with higher values of 93.2% sensitivity, 98.6% specificity, 98% PPV and 95.2% NPV confirms the reliability of accuracy & performance of HbChek hemoglobinometer (Figure 2).

A strong positive correlation between the two measurements devices and high accuracy of HbChek suggest that the newly developed Point of Care (POC) Hemoglobinometer, HbChek, can potentially replace a pathology laboratory analyzer for the purpose of measuring hemoglobin in blood samples. Keeping the performance of HbChek in view, the newly developed device demonstrated the potential to become a dependable tool for healthcare providers for measuring and monitoring hemoglobin levels of patients in conventional healthcare setups as well as in field studies.

Conflict of Interest: None.

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