PERFORMANCE EVALUATION OF VERI-Q RED HAEMOGLOBIN METER FOR POINT-OF-CARE HAEMOGLOBIN AND PACKED CELL VOLUME ESTIMATIONS

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Abstract: **Introduction:** Haemoglobin (Hb) and packed cell volume (PCV) are tests used in the assessment of anaemia. The Veri-Q haemoglobin meter is a new device in the point-of-care market used for the quantitative measurement of haemoglobin and packed cell volume. This study aimed to evaluate the performance of the Veri-Q haemoglobin meter for the assessment of haemoglobin and packed cell volume.

Materials and Methods: Haemoglobin and packed cell volume estimations of one hundred and eleven participants were determined using the Veri-Q Red haemoglobin meter and statistically compared with those obtained from the conventional method (gold standard).

Results: One hundred and eleven undergraduate students participated in this study, of whom 72 (64.9%) were females and 39 (35.1%) were males. The mean haemoglobin values calculated using the Veri-Q haemoglobin meter (11.97 ± 1.95 g/dl) were significantly lower than the values obtained with the conventional method (12.35 ± 1.66 g/dl) (t = 4.7549; p = 0.0001). Similar results were obtained with packed cell volume estimation. The performance indices of the Veri-Q haemoglobin meter were as follows: sensitivity (75.41% for Hb and 77.05% for PCV), specificity (28.0% for Hb and PCV), positive predictive value (PPV) (56.1% for Hb and 56.63% for PCV), negative predictive value (48.28% for Hb and 50% for PCV). The prevalence of anaemia in this study was 54.05%. Positive Likelihood Ratio (1.05 for Hb and 1.07 for PCV), Negative Likelihood Ratio (0.88 for Hb and 0.82 for PCV), Accuracy (54.05% for Hb and 54.95% for PCV). The Receiver Operative Characteristics (ROC) Area Under Curve (AUC) was 0.996 for Hb and 0.984 for PCV. A significant but weak positive correlation was found to exist between haemoglobin estimations using conventional and Veri-Q methods (r = 0.3013, P = 0.01); PCV (R = 0.2512, P = 0.07). The sensitivity of the device can be described as moderate while the specificity is low. The accuracy of the device is just average.

Conclusion: The Veri-Q haemoglobin meter demonstrates an average level of accuracy and a high AUC, making it potentially useful for field epidemiological studies.

Keywords: Veri-Q, performance indices, haemoglobin, packed cell volume, anaemia, point of care.

INTRODUCTION

Haemoglobin (Hb) is a crucial protein found in red blood cells, responsible for transporting oxygen from the lungs to tissues throughout the body. Each gram of haemoglobin can carry approximately 1.4 ml of oxygen, comprising 96% of the red blood cell's weight (1-3).

Measurement of Hb and packed cell volume (PCV) is routinely included in complete blood counts, essential for diagnosing and monitoring anaemia in patients. Anaemia can result from various pathological processes, including bleeding, micronutrient deficiencies, hydration imbalance, organ diseases, and hemolysis (4-7).

The VERI-Q Instrument (Manufacturer-Diaprax GmbH (sold by Micobiomed, South Korea), Wesel, Deutschland, 2015) is utilized for quantitatively measuring Hb levels. This device is suitable for both professional and self-testing purposes. It provides results within 5 seconds, offering precision, reliability, and ease of use. The Veri-Q-Red device boasts advantages such as quick results, requiring only a small blood sample (7 µl full blood), a measuring range of 5 - 25 g/dl,

including haematocrit indication, PC interface, affordability, and convenient storage of test strips at room temperature without the need for cooling (7).

Veri-Q haemoglobin test strips measure both Hb and haematocrit values in blood samples. However, the performance characteristics of this point-of-care machine have not been extensively documented in the literature, and its reliability and utility remain to be validated. Given that Hb and packed cell volume are commonly requested tests in hospitals, there is a critical need to compare the performance of the Veri-Q machine with conventional methods of Hb and packed cell volume estimations for patient management and field epidemiological studies.

Therefore, this study aimed to determine Hb and packed cell volume levels using the Veri-Q Red Point-of-Care device and compare the results with those obtained from conventional laboratory methods. The study seeks to assess the performance indices of the Veri-Q Red device to ascertain its reliability and utility in clinical and epidemiological settings.

Figure 1. Veri-Q RED Haemoglobin meter

MATERIAL AND METHODS

Study Setting

This study was conducted at Rivers State University (RSU) in Port Harcourt, Nigeria, a government-owned university located in the heart of Port Harcourt metropolis. The study population consisted of apparently healthy students of the university.

Study Design

The study adopted a cross-sectional design to collect data from participants.

Ethical Considerations

Informed consent was obtained from all participants before blood collection. Ethical approval was obtained from the Office of the Research Ethics Committee at the Rivers State University Teaching Hospital. All procedures were conducted in accordance with the institutional and/or national research committee's ethical standards and with the principles outlined in the 1964 Helsinki declaration and its later amendments.

Sample Collection

Three milliliters of venous blood were collected from each participant into ethylene diamine tetraacetic acid (EDTA) anticoagulant bottles. These samples were used for Veri-Q Red point-of-care device testing and conventional methods for haemoglobin and packed cell volume estimations.

Procedure for Packed Cell Volume Estimation by Microhematocrit Method

A capillary tube was immersed in the venous blood sample, allowing the blood to enter the tube via capillary action. The last 15mm of the tube was left unfilled.

The tube was sealed with sealant, ensuring no air was trapped between the sealant and the column of blood. The sealed tube was placed in a microhematocrit centrifuge with the sealed end facing the outer rim and centrifuged at 12000 g for 5 minutes.

The packed cell volume was determined using a microhematocrit reading device.

Procedure for Haemoglobin and Packed Cell Volume by Veri-Q Method

The pipette lip was securely inserted into the pipette. The top button of the pipette was pushed down to the first stage to collect the blood sample from the finger.

Subsequently, the top button of the pipette was carefully and slowly released to draw the blood into the lip. The top button was then pushed down to release the blood into the strip.

The results for haemoglobin and packed cell volume were read within 5 seconds using the Veri-Q Red device.

Procedure for Haemoglobin Estimation by Haemiglobincyanide Method

25 µl of blood was added to 5.0 mL of reagent, mixed, and left for 5 minutes. Absorbance was measured at 540 nm against a reagent blank. The absorbance of the HiCN standard was measured similarly.

The haemoglobin concentration was calculated using the formula: (Absorbance of test / Absorbance of standard) × Concentration of standard in g/dl.

Statistical Analysis

The data obtained were analyzed using GraphPad Prism software version 6.00 produced by GraphPad

Software Inc., USA. Data were presented as means and standard deviations, and comparison between means was done using t-test analysis. Performance indices were calculated using standard formulae.

RESULTS

A total of one hundred and eleven subjects participated in the study, comprising 72 (64.9%) females and 39 (35.1%) males. The mean Hb values measured using the Veri-Q haemoglobin meter (11.97 ± 1.95 g/dl) were significantly lower than those obtained from the conventional method (12.35 ± 1.66 g/dl) (t = 4.7549; p = 0.0001). Similar results were observed for Packed Cell Volume estimation (Table 1).

Table 2 presents the performance indices of the Veri-Q Red haemoglobin meter. The sensitivity of the point-of-care (POC) machine was 75.41%, specificity was 28.0%, positive predictive value (PPV) was 56.1%, and negative predictive value was 48.28%. The prevalence of anaemia in this study was found to be 54.05%.

Figures 2-5 depict the Receiver Operating Characteristic (ROC) curve of Veri-Q Red for haemoglobin and Packed Cell Volume (PCV). The Area Under Curve (AUC) was 0.996 for HB and 0.984 for PCV.

Figures 6 and 7 illustrate the Pearson correlation between haemoglobin and Packed Cell Volume estimations using the Veri-Q Red meter and conventional
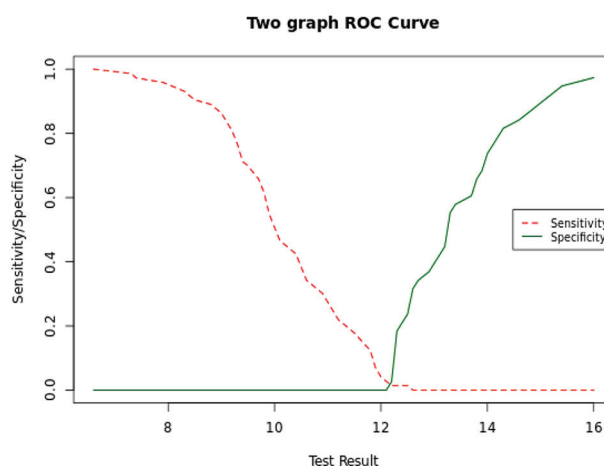

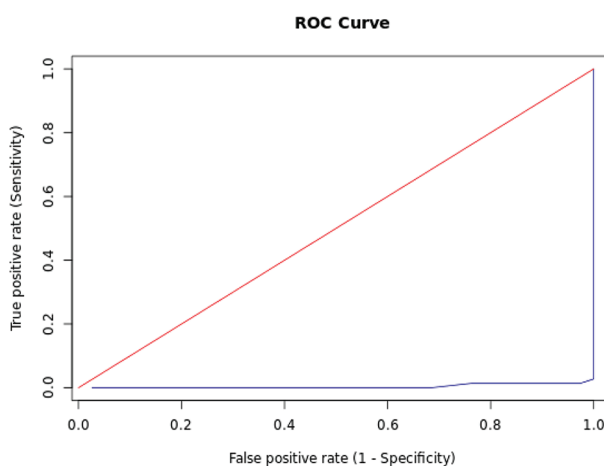*Figure 2*. *Sensitivity and Specificity ROC curve for Veri-Q haemoglobin estimation*

Figure 3. *Graph of ROC curve for haemoglobin estimation using Veri-Q meter*

methods. A significant positive correlation was found to exist between haemoglobin estimations using conventional and Veri-Q Red methods (r = 0.3013, p = 0.001); PCV (R = 0.2512, p = 0.007) (Figure 6). Similar results were obtained for PCV and the Veri-Q Red haemoglobin meter (Figure 7).
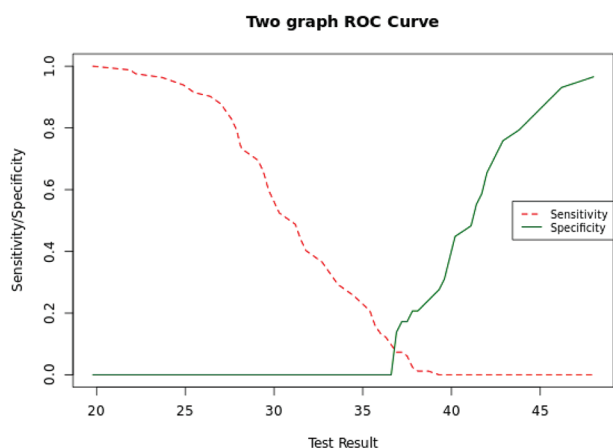
Table 1. *Mean values of Haemoglobin and Packed Cell Volume of the conventional and Veri-Q methods*

Methods	Hb(g/dl) Mean ± SD	PCV (%) Mean ± SD
Conventional	12.35 ± 1.66	36.48 ± 4.91
Veri-Q	11.97 ± 1.95	33.18 ± 6.43
T-test	4.7549	4.2951
P-values	0.0001***	0.0001***

Table 2. Performance indices of Veri-Q haemoglobin meter using conventional methods as gold standard

Statistic	Hb Value	Hb 95% CI	PCV Value	PCV 95% CI
Sensitivity	75.41%	62.71% to 85.54%	77.05%	64.50% to 86.85%
Specificity	28.00%	16.23% to 42.49%	28.00%	16.23% to 42.49%
Positive Likelihood Ratio	1.05	0.84 to 1.31	1.07	0.86 to 1.33
Negative Likelihood Ratio	0.88	0.47 to 1.64	0.82	0.43 to 1.55
Disease prevalence (*)	54.95%	45.22% to 64.41%	54.95%	45.22% to 64.41%
Positive Predictive Value (*)	56.10%	50.51% to 61.53%	56.63%	51.15% to 61.94%
Negative Predictive Value (*)	48.28%	33.31% to 63.55%	50.00%	34.54% to 65.46%
Accuracy (*)	54.05%	44.33% to 63.55%	54.95%	45.22% to 64.41%

(*) These values are dependent on disease prevalence.

Figure 4. *Sensitivity and Specificity ROC curve for Veri-Q Packed Cell Volume estimation*
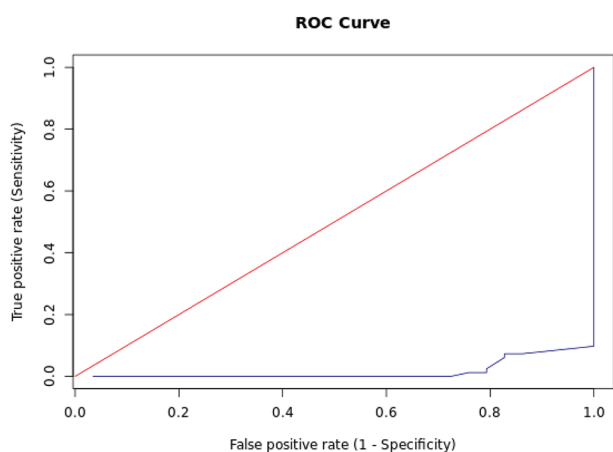
Figure 5. *Graph of ROC curve for packed cell volume estimation using Veri-Q meter*

Figure 6. *Pearson correlation of haemoglobin estimation using Conventional versus Veri-Q methods*
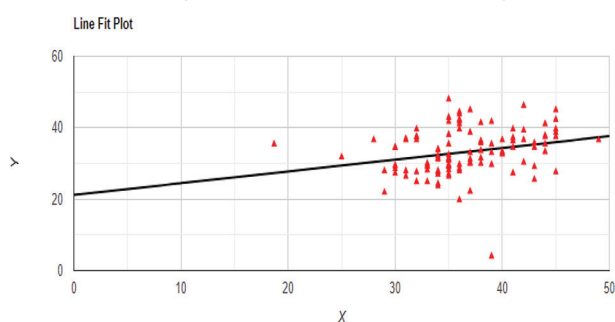
Figure 7. *Pearson correlation of Packed cell volume values using Conventional versus Veri-Q methods*

DISCUSSION

The Veri-Q haemoglobin meter is a new device designed for point-of-care testing, field studies, diagnostic, and clinical use in hospital emergencies, as well as for quick diagnoses of anaemia at home. The performance characteristics of this new device have not been encountered in the literature. This study represents the very first attempt to validate the equipment and determine its performance characteristics.

The sensitivity of the Veri-Q Red haemoglobin meter was found to be 75.4% for Haemoglobin and 77.0% for Packed Cell Volume. Sensitivity indicates the likelihood that a diseased patient has a positive result, meaning it will correctly give positive results for those with the disease condition. A sensitivity of 75% implies that out of one hundred people who have the disease, in this case, anaemia, seventy-five of them will be correctly diagnosed with this test device. In epidemiological or diagnostic studies, high sensitivity is useful to exclude a diagnosis because it will render few results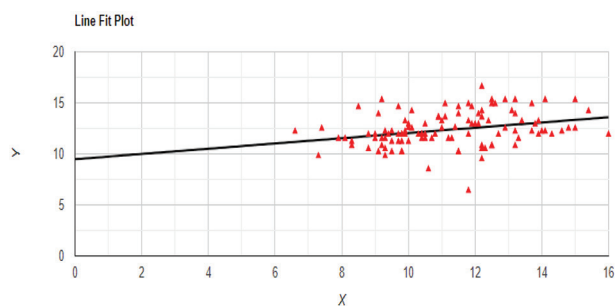 that are falsely negative. To rule out anaemia, clinicians might prefer a test with high sensitivity. The sensitivity of this device could be regarded as very good.

The specificity of the Veri-Q Red haemoglobin meter was found to be 28.0% for both haemoglobin and packed cell volume. Specificity refers to the likelihood that a healthy person has a negative test result. If one hundred persons do not have anaemia and the test is capable of giving a negative result for all of them (100% specificity), then the test is highly specific. A highly specific test is useful to confirm a diagnosis because it will have few results that are falsely positive. In this study, the specificity of the Veri-Q Red haemoglobin meter is as low as 28.0%. This means that the device can correctly identify 28% of true negative cases. In other words, if the testing device is used on a sample of individuals who do not have a certain condition or trait, it will correctly identify 28% of them as negative. The higher the specificity, the better the testing device is at accurately ruling out the presence of a specific condition or trait in individuals without it. Thus, it is not suitable to be used to confirm disease among apparently healthy subjects.

Receiver Operative Characteristics (ROC), which is a logistic regression model, is often employed to determine the best cutoff value for predicting whether a new observation is a failure (0) or a success (1). In this study, the AUC for haemoglobin is 0.996 while that of PCV is 0.984. This indicates that the Veri-Q Red haemoglobin meter is efficient and will be able to discriminate between positives and negatives.

The accuracy of the Veri-Q Red machine was determined to be 54.05% for Hb and 54.95% for PCV. The accuracy of the Veri-Q Red haemoglobin meter can be maximized by calibrating the equipment with reference material and by participating in external quality control programmes.

The positive predictive value (PPV) of the Veri-Q Red machine in this study was obtained as 56.10% for Hb and 56.63% for PCV. On the other hand, the negative predictive value for Hb was 48.28% and 50% for PCV. PPV is capable of predicting how likely it is for someone to truly be a patient in case of a positive test result, while Negative Predictive Value (NPV) can predict how likely it is for someone to truly be healthy in case of a negative test result (8).

In this study, the positive likelihood ratio (LR+) for Hb was 1.05 and for PCV 1.07, while the negative likelihood ratio (LR-) was 0.88 for Hb and 0.82 for PCV. The prevalence of anaemia was 54.95%. The study population consisted of apparently healthy adult students of both sexes. This prevalent rate of anaemia among the students of this University corroborates the study of Shill *et al*. (9), where a prevalent rate of 55.3% was reported among university students in Bangladesh. However, the prevalence of anaemia in this study is quite high compared with 28.9% reportedly recently among adults in a selected population in Lagos, Nigeria (10). In Ghana, a prevalence rate of anaemia was reported to be 45.1% among University students (11). The high prevalence of anaemia among students may be attributed to poor dietary habits, menstrual blood loss, and lack of awareness of iron deficiency and nutritional status (12).

CONCLUSION

In conclusion, this study revealed a high prevalence rate of anaemia when using the Veri-Q Red haemoglobin meter. Despite this, a significant positive correlation was found to exist between haemoglobin estimations using conventional and Veri-Q Red methods. However, the sensitivity of the Veri-Q device can be described as moderate, while the specificity is quite low. Additionally, the accuracy of the device was found to be average.

If properly validated, the Veri-Q-Red device has the potential to be an ideal point-of-care device for various medical settings, including blood banks, blood donation centers, general practitioners' offices, internists' practices, gynecologists' and perinatologists' clinics, as well as laboratory and home use. Further validation and quality control measures are necessary to ensure its reliability and effectiveness in clinical practice.

RECOMMENDATION

It is recommended that the Veri-Q Red haemoglobin meter undergo thorough validation and quality control measures to ensure its reliability and accuracy. If these measures are implemented successfully, the device can serve useful purposes in field epidemiological surveys and point-of-care settings.

Abbreviations

AUC - Area Under Curve
ROC - Receiver Operative Characteristics
PCV - Packed Cell Volume

Sažetak

EVALUACIJA PERFORMANSI VERI-Q HEMOGLOBINSKOG MERAČA ZA PROCENU HEMOGLOBINA I HEMATOKRITA NA MESTU PRUŽANJA POMOĆI

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Uvod: Hemoglobin (Hb) i hematokrit (Ht) su testovi koji se koriste u proceni anemije. Veri-Q hemoglobin merač je nov uređaj na tržištu za brzo testiranje, koji se koristi za kvantitativno merenje hemoglobina

i hematokrita. Ova studija ima za cilj procenu performansi Veri-Q hemoglobin merača za procenu hemoglobina i hematokrita.

Materijali i metodi: Procena hemoglobina i hematokrita kod sto jedanaest učesnika izvršena je pomoću Veri-Q hemoglobinskog merača i statistički upoređena sa vrednostima dobijenim konvencionalnom metodom (zlatni standard).

Rezultati: U ovoj studiji je učestvovalo sto jedanaest studenata osnovnih studija, od kojih je 72 (64,9%) bilo ženskog pola, a 39 (35,1%) muškog pola. Srednje vrednosti hemoglobina izračunate korišćenjem Veri-Q hemoglobinskog merača (11,97 ± 1,95 g/dl) bile su značajno niže od vrednosti dobijenih konvencionalnom metodom (12,35 ± 1,66 g/dl) (t = 4,7549; p = 0,0001). Slični rezultati dobijeni su i kod procene hematokrita. Performanse Veri-Q hemoglobinskog merača bile su kako sledi: osetljivost (75,41% za Hb i 77,05% za PCV), specifičnost (28,0% za Hb i PCV), pozitivna prediktivna vrednost (PPV) (56,1% za Hb i 56,63% za PCV), negativna prediktivna vrednost (48,28% za Hb i 50% za PCV). U ovoj studiji, prevalencija anemije je bila 54,05%, pozitivni odnos verovatnoće (1,05 za Hb i 1,07 za PCV), negativni odnos verovatnoće (0,88 za Hb i 0,82 za PCV), a tačnost (54,05% za Hb i 54,95% za PCV). AUC-ROC je bila 0,996 za Hb i 0,984 za PCV. Primećena je značajna, ali slaba pozitivna korelacija između procene hemoglobina korišćenjem konvencionalne i Veri-Q metode (r = 0,3013, P = 0,01); PCV (R = 0,2512, P = 0,07). Osetljivost uređaja može se opisati kao umerena, dok je specifičnost niska. Tačnost uređaja je samo prosečna.

Zaključak: Veri-Q hemoglobinski merač pokazuje prosečnu tačnost i visok AUC, što ga čini potencijalno korisnim za terenske epidemiološke studije.

Ključne reči: Veri-Q, performansni indeksi, hemoglobin, puni volumen eritrocita, anemija, „Point-of-Care" ispitivanje.

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