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ORIGINAL ARTICLE

Performance of Hb HemoCue Machine Compared to Automated Hematology Analyzer for Hemoglobin Measurements Among Adult Patients at Kilimanjaro Christian Medical Centre

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ABSTRACT

Background: Automated haematology analysers offer precise haemoglobin measurements, but are expensive and impractical for field, point of care, primary care and remote settings use. The portable and cost-effective Hemocue device provides an alternative. Comparing their accuracies is crucial to prevent diagnostic discrepancies and misdiagnoses. This study aimed to determine the accuracy of Hb HemoCue machine by comparing its performance to automated analyser at Kilimanjaro Christian Medical Centre (KCMC) clinical laboratory where both equipment are used.

Methodology: A cross-sectional study was conducted at KCMC Clinical Laboratory among adult patients whose haemoglobin concentrations were measured from May to June 2024. Haemoglobin levels were estimated using two distinct methods: Hb HemoCue machine and automated haematology analyser.

Results: Haemoglobin (Hb) concentration values obtained from the HemoCue machine and the automated analyser, had a mean difference of 0.001 g/dL (95% CI: -0.036 to 0.038), t value of 0.062, and a *p-value* of .95, indicating a non-statistically significant differences between the two measurement methods. The Bland-Altman plot analysis indicated that the mean difference (bias) between the two methods was 0.0012 g/dL, and the limits of agreement ranged from -0.481 to 0.482 g/dL, suggesting that the HemoCue machine tends to slightly overestimate Hb values compared to the automated haematology analyser. The Pearson correlation coefficient for the Hb concentrations measured using HemoCue and automated analyser was 0.995, indicating a very strong positive correlation. The HemoCue demonstrated a sensitivity of 98.3%, specifity of 90.4%, positive predictive value of 95.9% and a negative predictive value of 95.9%, indicating high performance accuracy of HemoCue in diagnosing anaemia.

Conclusion: The study revealed strong agreement between HemoCue and automated haematology analyser for measuring haemoglobin concentrations. Both methods demonstrated high diagnostic accuracy suitable for clinical use. Although HemoCue slightly overestimated haemoglobin, this difference was deemed insignificant. The study endorses HemoCue as a reliable tool for haemoglobin concentration measurement alongside and in lack of automated analysers.

BACKGROUND

Anaemia is a prevalent global health issue which affects approximately 24.3% of the global population, equating to 1.92 billion individuals.[1] This condition is notably prevalent in low- and middle-income countries, with significant variations across regions and demographic groups.[2–4] The most highly affected groups includes children aged younger than 5 years and women.[1] The Global Burden of Disease article highlights that anaemia is a leading cause of years lived with disability (YLDs), emphasizing its impact on global health.[1]

In sub-Saharan Africa, the prevalence of anaemia is particularly higher than other regions in the world.[5] The overall prevalence among children aged 6 to 59 months has been reported to be 64.1%.[6] Western sub-Saharan Africa and Central sub-Saharan Africa report the highest prevalence rates.[6,7] In these regions the highest burden of anaemia is attributed to factors such as nutritional deficiencies, infectious diseases, and limited access to healthcare services.[3]

Tanzania, mirrors this regional anaemia trend. While specific national prevalence data for anaemia in adults is limited, a study indicate a significant burden among hospitalized elderly persons. A study conducted at a tertiary psychiatric hospital in Tanzania found that 79.5% of hospitalized adults aged 60 years and above had anaemia, with a significant proportion experiencing moderate to severe forms.[8] Furthermore,

recent national health surveys estimate the prevalence of anaemia among children under five years of age to be approximately 38%[9] and among pregnant women to be approximately 57%.[10,11]

Management of anaemia depends on the underlying cause and severity of anaemia. Mild anaemia may be managed through intake of iron and folic acid rich diets.[12] The WHO recommends daily oral iron supplementation with 60 to120mg of elemental iron and 400µg of folic acid to prevent and treat iron-deficiency anaemia especially among pregnant women.[13] In cases where anaemia results from chronic diseases such as chronic kidney disease or inflammatory disorders, treatment focuses on managing the underlying condition.[14] For individuals with severe anaemia, e.g., haemoglobin levels below 7g/dL, blood transfusions may be necessary, especially if there are signs of decompensation or underlying conditions such as sickle cell disease or severe malaria.[13]

The documented high burden of anaemia in sub-Saharan Africa and Tanzania highlights the need for effective diagnostic tools to accurately assess anaemia in the various settings, especially rural settings where people are more affected by anaemia due to poor access to healthcare, poverty and dietary deficiencies.[15]

The most trustworthy metric for screening people for anaemia and gauging the effectiveness of medical and dietary interventions is haemoglobin (Hb) measurements. Haemoglobin levels are one of the most accurate markers of anaemia and are frequently used to identify anaemic people and monitor how well interventions are working.[16,17]

The World Health Organization colour scale, Sahli's method, HemoCue, and clinical examination for pallor are frequently used techniques to estimate haemoglobin in a community, and primary healthcare facilities.[18,19] However, these techniques have a number of drawbacks, including poor accuracy, complexity, and high expense.[19,20] Accurate quantitative diagnostic tests can verify the diagnosis of anaemia, nevertheless, highly accurate techniques either depend on constant electricity supply, use costly or toxic chemicals and consumables, or require constant quality control and needs to be operated by trained personnel.[16] In most cases, these are not appropriate for use in the majority of point of care and primary health-care settings with limited resources.[16,17]

In clinical laboratories, automated haematology analysers are typically used to measure Hb concentrations. These instruments are highly accurate and dependable, but they are also costly and impractical for field, point of care and primary healthcare use.[17,21] On the other hand, the HemoCue device has been widely used in field settings with limited resources due to its portability, ease of use, and reasonable cost. Additionally, the HemoCue device gives an instant numerical Hb value with just a tiny drop of capillary or venous blood.[16]

At Kilimanjaro Christian Medical Centre (KCMC) Clinical Laboratory, HemoCue machine is used alongside the automated haematology analyser. To save costs of operation, the Hb HemoCue machine is used when the test request needs only haemoglobin levels to be measured while the automated analyser is used when the test request needs a broader haematological profile to be analysed. It is crucial to assess the accuracy of HemoCue compared to that of automated haematology analysers in haemoglobin estimation. Understanding the differences between these two methods is essential for preventing misdiagnoses and understand if there are significant results discrepancies between Hb values when measured using the two different equipment.

Additionally, in Tanzania, there is limited published data from studies comparing the performance of HemoCue and automated haematology analysers among patients being tested for haemoglobin testing in clinical laboratories, despite the HemoCue machine's widespread use. This study compared Hb HemoCue performance to that of an automated haematology analyser among adult patients undergoing haemoglobin concentrations testing at KCMC clinical laboratory.

MATERIALS AND METHODS

Study Area

This study was conducted at KCMC Clinical Laboratory, which is a well-equipped medical facility with the necessary infrastructure and expertise to conduct haemoglobin tests using both HemoCue and automated analyser. Kilimanjaro Christian Medical Centre (KCMC) is a referral zonal hospital situated in Moshi, a town located within Kilimanjaro Region in Tanzania, East Africa. Kilimanjaro Christian Medical Centre (KCMC) offers a wide range of inpatient and outpatient medical services. It serves over 15 million people in the northern zone of the country and beyond attending outpatients and 500 to 800 inpatients per day. The hospital has a bed capacity of 630. The KCMC clinical laboratory is one of the hospital's departments which supports patient care by conducting a wide range of diagnostic investigations across multiple specialized sections. The laboratory's sections include: Clinical Biochemistry, Microbiology, Serology, Blood Transfusion, Parasitology, Molecular Diagnostics, and Haematology. In Haematology section blood samples are analysed to diagnose conditions like anaemia, leukaemia, and clotting disorders. The laboratory maintains high standards through participation in external quality assurance programs, such as United Kingdom National External Quality Assessment Service (UKNEQAS) and the College of American Pathologists (CAP) surveys. Annual audits by organizations like Family Health International 360 (FHI360) further ensure adherence to international quality benchmarks.

Study Design and Sampling Procedures

A cross-sectional study was conducted from May to June 2024 to compare haemoglobin concentrations and measurement accuracy of HemoCue machine to that of an automated haematology analyser among adult patients. A convenient sampling technique was used to obtain participants whose blood samples were used in this study. Individuals aged 18 years and above, who came to KCMC Clinical laboratory with blood test requests for full blood count and consented to participate in this study were included. A total of 170 individuals were enrolled in this study and in total, 170 blood samples were collected and analysed for haemoglobin concentrations.

Sample Size Estimation

Sample size determination was done by the use of Cochran's formula

$$n = \frac{Z^2 p(1-p)}{e^2}$$

Where:

n = required sample size

Z = Z-score, which corresponds to the desired level of confidence (e.g., for a 95% confidence level, Z is approximately 1.96)

p = estimated proportion of the population that has the attribute of interest (79.5% obtained from anaemia study among elderly patients in Tanzania [8])

e = margin of error (desired precision) 0.05 (5%)

Therefore, from Cochran's formula

$$\text{Sample size} = \frac{1.96^2 \times 0.5\,(1-0.795)}{0.05^2}$$

$$= 157.50$$

Therefore, the minimum sample size (n) was = 157 individuals.

Inclusion and Exclusion Criteria

In this study, adult individuals from 18 years and above were included. This group was selected to increase the relevance of studying anaemia and exploring HemoCue accuracy across a broad age range as it has been previously restricted mainly to children and pregnant women. Also, this group was selected for its convenience when drawing venous blood samples to minimize errors that may originate from difficulties when collecting blood from groups such as children to ensure high quality blood samples were collected. In this study, patients with difficult veins, pregnant women and those who did not consent to participate were excluded.

Ethical Approval

Ethical approval for this study was obtained from the KCMC University Research Ethics and Review Committee (KU-RERC) (certificate number UG 105/2024). Written informed consent forms were given to potential participants, and those who gave consent were included in the study. Participants' information was only accessed by the research team and only identification numbers were used in data compilation to ensure confidentiality.

Data Collection

Permission for data collection was sought from KCMC Hospital and the Clinical Laboratory management. A simple data collection log was used to obtain participants' information including a unique identifier, age and gender and Hb concentration.

Collection of Venous Blood

Blood collection procedure was well explained to the patient followed by the process of blood collection. A tourniquet was applied just above the venepuncture site and sterile alcohol swabs used to clean the area of venepuncture. Blood was drawn from an antecubital, dorsal metacarpal or great saphenous vein into an ethylene diamine tetra-acetic acid (EDTA) vacutainer using a sterile syringe. Blood sample tubes were labelled with patient information including the study identification number and sent to the clinical laboratory for analysis.

Laboratory Procedures

The collected samples were tested for haemoglobin concentration (Hb) using both automated haematology analyser (AHA) (Mindray_BC-5380, Shenzhen Mindray Bio-Medical Electronics Co. LTD) followed by Hb Hemocue machine (HemoCue 201+, HemoCue AB, Sweden). The results of haemoglobin values obtained from both the Hemocue machine and the automated haematology analyser for each patient were recorded in the data collection log.

For quality control, daily maintenance and daily quality control of automated haematology analyser was performed. Routine thorough clean-up of equipment was performed as required in the daily maintenance standard operating procedure. Daily quality control was performed by analysing three quality control samples (BC-5C Hematology Control, Mindray) which provide measures of high, normal and low haematological parameters.

Statistical Analysis

Data entries were double checked and final database was cleaned and analysed using Statistical Package for Social Sciences (SPSS) software version 25 (SPSS Inc, Chicago, Illinois, United States of America). The mean of differences (bias), standard deviation of differences (SD) and limits of agreement between the HemoCue and the automated haematology analysers readings were calculated using Bland-Altman model. Pearson correlation analysis was performed and correlation coefficient (r) was calculated. Paired t-tests tests were used to compare the difference between the mean Hb concentrations values estimated by HemoCue and the automated haematology analyser. The automated haematology analyser was considered as the reference method against which the accuracy of the HemoCue was determined. The sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) of HemoCue machine were calculated. Frequency distributions of categorical variables such as gender and age groups were also determined. Results were presented in figures, and summarized in tables, and significant differences or correlations were determined at $P<.05$.

Variables

The dependent variables included haemoglobin concentrations and independent variables included method of estimation of haemoglobin concentrations (Hemocue and automated haematology analyser) and demographic variables (age and gender). The haemoglobin concentrations were presented as continuous variables and age and gender were treated as categorical variables.

RESULTS

A total of 170 adults of 18 years and above participated in this study. All 170 participants were tested for haemoglobin concentrations using both the Hb HemoCue machine and automated haematology analyser. Distribution by gender was nearly equal, with 52.0% being female individuals. The participants' mean age was 52.2 years and standard

deviation (SD) was 20.05 years (Table 1).

TABLE 1: Study Population's Characteristics (N=170)

Variable	Frequency	Percentage
Age (years)		
18-30	36	21.2
31-40	24	214.1
41-51	8	24.7
>51	102	260.0
Mean (SD)	52.2(20.05)	
Sex		
Male	81	247.6
Female	89	252.4

Descriptive statistics were calculated for Hb concentrations from both HemoCue and the automated haematology analyser. For 170 readings, the mean Hb concentration value for HemoCue was 11.606g/dL with a standard deviation of 2.461g/dL and standard error of mean was 0.1888, while for the same number of readings, the mean Hb concentration value for automated haematology analyser was 11.605g/dL with a standard deviation of 2.397g/dL and standard error of mean was 0.1839 (Table 2). The mean difference for the two equipment measurements was 0.001g/dL.

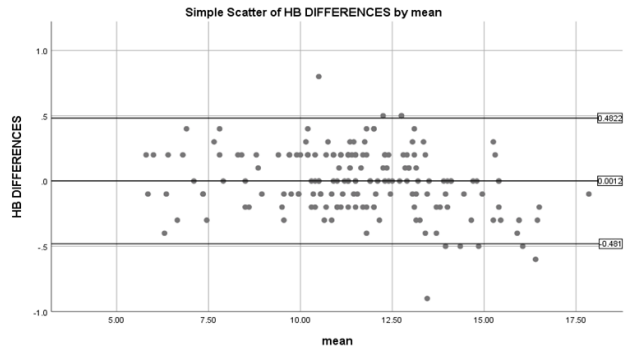
The Pearson correlation coefficient for the HB concentrations measured using HemoCue machine and automated haematology analyser was 0.995 and this correlation was statistically significant $P<.001$. A pair sample t-test was conducted to compare the difference in Hb concentration values obtained from HemoCue machine and the automated haematology analyser. The result showed a mean difference of 0.001g/dL (95% Cl: -0.036 to 0.038). The t value was 0.062, with a P-value of 0.95, indicating that the differences between the two Hb concentration measurement methods are not statistically significant.

TABLE 2: Pearson Correlation's Comparison of Haemoglobin Concentrations Measured Using Hemocue and an Automated Haematology Analyser (N=170).

	Minimum	Maximum	Mean	Std. Deviation	Std. Error Mean
Hematology analyzer(g/dl)	5.8	17.8	11.605	2.3974	0.1839
HemoCue machine(g/dl)	5.7	17.9	11.606	2.4613	0.1888

Data in Figure 1 below represents the differences (automated haematology analyser–HemoCue) for the average Hb results. The middle solid line represents the mean difference between the measurements (bias), while the upper and lower lines indicate the 95% limits of agreement (LOA) between methods. The mean difference (bias) was 0.0012g/dL, with the limit of agreement ranging from -0.481 to 0.482g/dL. This suggest that HemoCue tends to slightly overestimate Hb values compared to the automated haematology analyser, but the differences are generally small and within acceptable limits.

FIGURE 1: Bland-Altman Comparison of Hemoglobin Concentrations Measured Using Hemocue and an Automated Hematology Analyzer



In this study, we evaluated the accuracy of the diagnostic performance of the HemoCue haemoglobinometer compared to an automated haematology analyser for haemoglobin estimation. HemoCue demonstrated a sensitivity of 98.3% and specificity was 90.4%. The PPV was 95.9% and the NPV was 95.9%. The absolute number results for the performances of the two machines are as summarized in the contingency Table 3.

TABLE 3: Number of Anaemic Patients

	HemoCue		Total
Automated Haematology Analyser	Anaemic	Non-anaemic	
Anaemic	116	5	121
Non-anaemic	2	47	49
Total	118	52	170

DISCUSSION

The results of this study have important implications for clinical practice, particularly in settings where different methods are used interchangeably and in low resource and point of care settings where simple yet reliable methods are needed for appropriate diagnosis of anaemia.

While the results of this study show that, the HemoCue machine slightly overestimates Hb concentration values (mean difference 0.001g/dL), this overestimation is minimal and may not be clinically relevant in the current study setting. This observation is supported by the high sensitivity (98.3%) of the Hemocue machine described in this study. Another study reported a mean difference of 0.2g/dL, for Hb concentration measured by HemoCue compared to an automated analyser Sysmex KN21TM, reinforcing the observation that while the HemoCue

is reliable, it systematically reads slightly higher than automated analyzers.[22]

The results of this study show, both the HemoCue machine and the automated haematology analyser provide reliable and consistent Hb measurements. Although there is a slight variation in Hb concentrations measured by the two methods, the differences are within clinically acceptable limits. The Pearson's correlation coefficient approached 1 (r=0.995; P<.001), indicating a significantly strong positive correlation between the Hb concentration values measured by the two equipment. Our study's findings are corroborating with the paired sample t-test results which revealed a lack of statistically significant difference between the Hb values obtained from the HemoCue machine and the automated haematology analyser, with a mean difference of 0.001 g/dL (95% CI: -0.036 to 0.038), t value of 0.062 and P-value of 0.95.

Concurrent with the current study's findings, other studies also showed that the Hb concentration results measured using HemoCue machine significantly correlate to the Hb concentration results measured by automated analysers as the standards,[22–25] supporting the reliability and accuracy of HemoCue in the places where automated analysers are impractical. Contrary to the current study's findings, other studies reported a lack of or weak correlation between haemoglobin concentrations when measured by HemoCue and automated analyser, probably because they compared certain specific populations or compared different types of samples e.g. capillary versus venous blood.[26,27]

The Bland-Altman plot analysis indicated that the mean difference (bias) between the two methods was 0.0012g/dL, and the limits of agreement ranged from -0.481 to 0.482g/dL. This analysis highlights the variability between the two measurement techniques and emphasizes that, while the mean difference is minimal, there is a substantial range of agreement which may need to be given consideration during clinical interpretation of results depending on how critical the case is. The differences are generally small as they are within 0.5 limits of agreement which is within the acceptable limits (±1).[24,28] These findings concurred with what Salmond et al had reported.[28] Other studies carried out in Khartoum and Khammouane Province in Lao among pregnant women and children respectively demonstrated rather higher and therefore poor limits of agreement (bias of 1.17 LoA ± 1.57 and bias of 6.1g/L and LoA −11.5g/L to 23.7g/L respectively) for venous blood samples when Hb was estimated using HemoCue and automated analyser.[24,29] Unlike the current study, Adam et al compared HemoCue and Sysmex automated analyser and the different results may also be subjected to other factors such as the competence of the person performing the test and the performance of the Sysmex analyser in comparison to that of HemoCue. Furthermore, it is suggested that capillary blood sampling may result in pre-analytical errors which can influence results for point of care devices.[30]

The findings of this study have proven a high accuracy for HemoCue haemoglobinometer. The HemoCue demonstrated a sensitivity of 98.3%, indicating a high true positive rate for detecting low haemoglobin levels. Similarly, the specificity was 90.4%, reflecting a strong ability to correctly identify individuals without anaemia. The PPV was 95.9%, suggesting that anaemia detected by HemoCue result is highly likely to be accurate. The NPV was also 95.9%, meaning that a negative result reliably indicates the absence of anaemia. The current study's findings support the use of both methods for Hb measurement using venous blood in clinical settings. However, clinicians should consider cross-verifying critical Hb values with an automated analyser when possible. This study's findings are partly consistent with other studies assessing the accuracy of HemoCue devices. A study conducted in Nigeria among blood donors reported hemocue to have the sensitivity of 98.2% and specificity of 98.2%.[31] Another study by Ziemann et al. reported a sensitivity of 18.6% and specificity of 99.8% for HemoCue in blood donor screening, with an accuracy of 98.7%.[32] Similarly, a study conducted among women in Peru found a sensitivity of 71.1% and specificity of 81.7% for the HemoCue,[33] with a positive predictive value of 94.4% and a negative predictive value of 94.1%.

The observed discrepancies are probably because in the current study, a lot of factors were kept the same. For instances, only venous blood samples were used for both analysers and the same person operated the equipment during measurements. Additionally, the tests were performed by qualified laboratory technologists in an accredited laboratory, which implies that there are high performance standards.

Policy-wise, while HemoCue is valuable for its convenience and rapid results, automated analysers should be preferred for detailed diagnostics and critical decisions. Training healthcare providers to recognize and interpret these potential differences can enhance patient safety and care quality. The use of point of care devices, however, should fulfil some basic criteria, including economic, clinical, and regulatory issues; appropriate training of the users and knowledge of test requirements, performance, limitations, and potential interferences; the use of venous instead of arterial sampling, when possible; and a rigorous quality assessment, which should be under the responsibility of laboratory professionals.[34,35]

Strengths of the study

This study was able to compare HemoCue with the automated haematology analyser which is the gold standard tool for Hb estimation. The study's focus on a portable, cost-effective device like the HemoCue is particularly pertinent for low-resource environments, such as rural areas in Tanzania.

Limitations

This study compared Hb concentrations and accuracy of HemoCue and automated haematology analyser using only venous blood. Further studies can be conducted in this setting to compare the performance of the two equipment and the potential for results variations when capillary blood is used compared to when venous blood is used or when both blood samples are used. This study predominantly focused on adults aged above 18 years and venous blood samples. Future research should explore how age, sex, and different clinical conditions could influence Hb measurements obtained from both

HemoCue and the automated haematology analysers.

CONCLUSION AND RECOMMENDATION

The study concludes that there is a high level of agreement between the HemoCue and automated haematology analyser, Mindray BC-5380 in measuring haemoglobin concentrations. Both methods demonstrate excellent diagnostic accuracy and can be reliably used in clinical settings for Hb estimation. The slight overestimation by the HemoCue is negligible, and thus, it is a valid tool for Hb measurement alongside the automated haematology analyser. For policy and practice, this study's findings recommend HemoCue for use as a point of care device, for determining haemoglobin measurements in resource limited areas as well as critical care areas of health facilities following proper training of healthcare providers and strict adherance to regulatory guidelines.

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