ORIGINAL ARTICLE

Validation of new invasive digital hemoglobinometer for hemoglobin estimation as point-of-care device among pregnant women in a facility setting India

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ABSTRACT

Background: Anemia poses a significant health challenge for pregnant women (PW), and accurate and timely diagnosis is essential for effective management. **Objective:** The objective was to assess the diagnostic validity of the new digital hemoglobinometer for hemoglobin against laboratory-based hematology autoanalyzer among PW. **Methodology:** The study was conducted at a secondary-level healthcare facility among 204 pregnant women to be sampled conveniently, their sociodemographic and iron intake data collected, and hemoglobin levels assessed using a digital hemoglobinometer (Device A) and a hematology analyzer. Specificity, sensitivity, PPV, NPV, diagnostic accuracy, and method agreement were evaluated via Bland-Altman analysis and Lin's concordance correlation coefficient. **Results:** The proportion of anemia using the Device A was 64.7% while the hematology analyzer reported a proportion of 52.9%. Device A showed a sensitivity of 97.22%, specificity of 80.30%, and diagnostic accuracy of 86.3%, with substantial agreement indicated by Cohen's kappa coefficient (kappa = 0.72) and the weighted kappa coefficient for different grades of anemia was 0.67. Bland-Altman analysis revealed a mean difference (bias) of -0.28 (± 0.5) between the two methods, with limits of agreement at -1.24 and 0.68. Lin's concordance correlation coefficient of absolute agreement was 0.91. **Conclusion:** The DH showed high sensitivity and diagnostic accuracy for anemia detection in PW, with substantial agreement with the hematology analyzer. It offers a convenient and rapid alternative for POC hemoglobin estimation in resource-constrained settings.

KEYWORDS
Point-of-care testing, Anemia, Maternal Health, Diagnostic Accuracy, Screening

INTRODUCTION

Anemia poses a worldwide public health concern with significant implications for pregnant women. In India, maternal and child health remains a priority, and anemia among pregnant women continues to pose a substantial challenge. Adequate monitoring and timely intervention are crucial to address this issue effectively. Currently, anemia is diagnosed either by measuring Hb or by hematocrit i.e., packed cell volume. The gold standard for Hb estimation remains the cyanmethemoglobin method. (4) However, there is always a search for a simple, safe, accurate, affordable Hb testing tool that can be very effective in screening programs for anemia. An automated hematology analyzer is regarded as the standard method for the hemoglobin estimation in clinical laboratories next to the cyanmethemoglobin method (5). Hematology analyzers require access to laboratory facilities. Traditional laboratory-based methods require time and resources. Most pregnant women seek care at primary healthcare facilities where such services are often unavailable. At the primary level /field, inadequate blood samples, improper transportation, and inappropriate storage conditions make it difficult to diagnose anemia. This leads to a delay in the initiation of treatment and reduces the overall productivity across all age groups. (6)

Point-of-care technology (POCT) is essential for use in rural settings, blood donation events, national surveys, large-scale screening camps, and health programs at the national level. POCT for the hemoglobin estimation is a valuable tool in antenatal care, enabling swift assessment and management of anemia. POCT can be effective, convenient, easy to operate with minimum bias, can be performed in all weather conditions, and gives rapid results (7).

The objective of this study was to assess the diagnostic validity of invasive DH (Mokshit CHANDA AM005A) for Hb estimation against laboratory-based hematology autoanalyzer (sodium lauryl sulphate) among pregnant women in a secondary health facility in India. (9,10).

MATERIAL & METHODS

Study design & setting: This study was a community-based cross sectional conducted at a 50-bedded secondary-level healthcare facility, specifically a subdistrict hospital Ballabgarh, located in Haryana, India among Pregnant women.

Study period: This study was conducted between July to August 2023.

Study population: We recruited pregnant women from antenatal clinics of the centers through convenient sampling until reaching the desired sample size. The study included pregnant women in any trimester of pregnancy, excluding those with known hemoglobinopathies and chronic illnesses such as renal failure, liver failure, and cardiac diseases. The inclusion criteria did not impose any restrictions on the gravid index of the pregnant women participating in the study.

Sample size: Sample size was calculated using the mean difference and SD from existing literature on validation of these devices. With the SD of difference as 0.1 (1.1), alpha error of 5%, power 80% and 2.8 as maximum allowed difference, the required sample size was 164. A total of 204 pregnant women was enrolled, accounting for a 20% non-response rate.

Data collection & procedures: Sociodemographic information and past iron intake data were gathered through a pretested semi-structured interview schedule administered via Epicollect5 mobile application. A skilled laboratory technician conducted the collection of capillary and venous blood samples from all participating pregnant women at the designated site. Blood was drawn from the left hand of the study participants after removing the rings, relaxing and warming of the palm. Under strict aseptic precautions, the middle finger of left hand was pricked with the help of a sterilized, unused lancet. A finger prick was performed on the lateral side of the fingertip. Using a sterilized gauge piece, the first and second drop of blood was discarded. Gentle pressure was applied to the fingertip, microcuvette of invasive digital hemoglobinometer (DH) (Mokshit CHANDA AM005A) was filled with the third drop of blood. All necessary guidelines pertaining to hemoglobin estimation using microcuvettes

for digital hemoglobinometer device A was followed. Two milliliters of venous blood was collected from the ante-cubital vein into EDTA vacutainer and was processed (hemoglobin estimation) at subdistrict hospital for hemoglobin estimation using auto-analyzer Sysmex xs-1000i Automated Analyser (non-cyanide SLS method) on the same day, ensuring completion within six hours of collecting blood sample. All instruments were calibrated before, during and at the end of the study for hemoglobin estimation. Appropriate controls were used for calibration purpose. We assessed and plotted all three tiers of internal quality control samples (normal, low, and high) on the Levy Jennings (LJ) plot. Notably, all values were observed to fall within the two standard deviation range on the LJ plot. Digital hemoglobinometer device A works on absorbance photometry. The method involves measuring absorbance of whole blood at the Hb/HbO2 Isosbestic Point, utilizing microcuvette technology. The device detects the hemoglobin range between 0-25gm/dl and maximum volume of sample required is less than 10µL (one full blood drop). The device was designed to operate at working temperature range of 10-40°C. The device shows results within 7 seconds, and it can store data in memory for up to 1,000 tests.

Statistical analysis: Data were exported to Microsoft Excel and analyzed in STATA 18 statistical software. For the sociodemographic details, a descriptive analysis was done. The results of Hb estimation were expressed as gm/dL. The proportion of anemia was reported with 95% confidence interval (CI). Accuracy of automated analyzer and Hb by digital hemoglobin meter – device A was assessed by specificity, sensitivity, positive predictive value (PPV), and negative predictive value (NPV) compared with automated analyser. Furthermore, Bland–Altman graphs, including limits of agreement, were generated to evaluate the agreement between methods across the range of hemoglobin values. A p-value less than 0.05 was deemed statistically significant. Additionally, Lin's concordance correlation coefficient (CCC) of absolute agreement was calculated, accompanied by a 95% CI.

Ethical Consideration: The research protocol received approved from the Institutional Ethics Committee of All India Institute of Medical Sciences, New Delhi, India. Written informed consent was secured from all participants involved in the study.

RESULTS

The study enrolled 204 pregnant women were enrolled. The mean (SD) age of the participants was 25.3 (9.8) years. Among the participants, 171 (83.8%) were in the age group of 18-28 years. The majority of the participants belonged to other backward class (44.1%), from joint family (66.1%), having pukka house (92.1%), having secondary level of education (27.5%) and were homemakers (97%) (Table 1). The mean (SD) body mass index (BMI) of the participants at the time of data collection was 22.4 (4.2) Kg/m^2 . A substantial 64.8% of participants had taken iron supplementation in the current pregnancy, and the median (IQR) duration of iron intake was 1 (0.6 - 3) months.

The proportion of anemia using digital Hemoglobinometer and hematology analyzer was 64.7% and 52.9%, respectively(Table 2). The sensitivity for digital hemoglobinometer - Device A for the detection of anemia as against the hematology analyzer was 97.2 % (95%CI: 96.3 – 100.0). The specificity of digital hemoglobinometer was 80.3% (95%CI: 75.0 – 85.9). The PPV and NPV was 72.9% (95%CI: 66.8 – 79.0) and 98.1% (95%CI: 95.9 – 99.5), respectively. Diagnostic accuracy was 86.3% (95% CI: 81 – 90.4). Likelihood ratio of a positive test was 3.6 (3.4 – 3.9). The unweighted cohen's kappa was 0.72, and the weighted cohen's kappa coefficient for different categories of anemia (no/ mild/ moderate/ severe) was 0.67. The mean (SD) of Hb values using a digital hemoglobinometer was 10.4 (1.2) g/dL and autoanalyzer was 10.6 (1.3) g/dL, respectively. The mean difference/bias (SD) was -0.28 (± 0.5). The upper and lower and limit of agreement was -1.24 and 0.68, respectively (Figure 1). The test of normality was rejected with a p-value of <0.001. Lin's concordance correlation coefficient of absolute agreement was 0.91 (0.88 – 0.93).

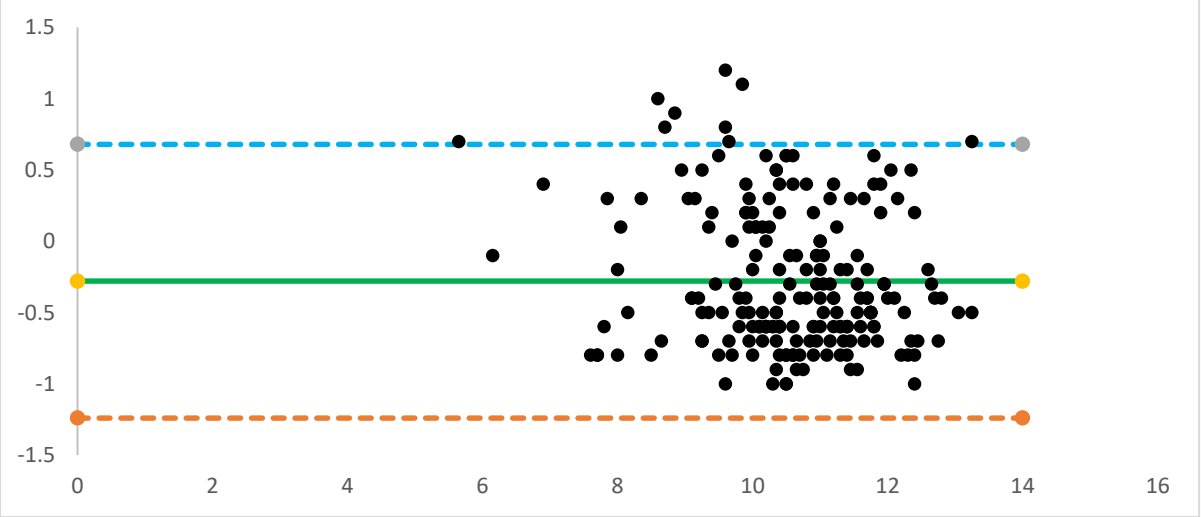
Table 1: Socio- demographic characteristics of the study participants

Variable	Category	Frequency	Percent (%)
Age in years	18-28	171	83.8
	29-36	33	16.1
Caste	General	65	31.9
	Other Backward Class OBC	90	44.1
	Scheduled Castes	49	24
Type of Family	Joint Family	135	66.1
	Nuclear Family	69	33.8
Type of House	Pukka	188	92.1
	Semi Pakka	16	7.8
	Kachha	0	0
Ownership of House	Own House	112	54.9
	Rented House	92	45.1
Electricity Supply	Yes	194	95.1
	No	10	4.9
Education Status	Illiterate	41	20.1
	Primary Education	69	33.8
	Secondary Education	56	27.5
	Under graduate	31	15.2
	Degree/ PG	7	3.4
Occupation	Employed	123	60.3
	Homemaker	81	39.7

Table 2. Proportion of anemia and mean (standard deviation) of hemoglobin determined by the digital Hemoglobinometer, and hematology analyzer among the pregnant women (N=204)

Hemoglobin concentration, g/dL	Digital hemoglobinometer	Hematology autoanalyzer
Mean±SD	10.4 ± 1.2	10.7 ± 1.3
Range	6.0 -13.6	5.3 - 13.5
Proportion of anemia (95% CI)	64.7% (57.8-71.0)	52.9% (46.0-59.7)
No Anemia, n (%)	72 (35.3)	96 (47.1)
Mild anemia, n (%)	72 (35.3)	60 (29.4)
Moderate anemia, n (%)	58 (28.4)	45 (22.1)
Severe anemia, n (%)	2 (1)	3 (1.5)
Total, n(%)	204 (100%)	204 (100%)

Figure 1: Bland–Altman plot showing difference in hemoglobin concentration assessed by digital hemoglobinometer Device A and hematology analyzer



DISCUSSION

This study assessed the diagnostic accuracy of digital hemoglobin meter device - A against hematology analyzer (sodium lauryl sulphate) to estimate hemoglobin among pregnant women at a secondary healthcare facility of India. A study has reported the bias for this device as (limits of agreement) as -0.7gm/dL to + 0.7gm/dL. (11) Our study reported bias as -0.28 which was similar to the finding of previously conducted studies done where validity of digital hemoglobinometer was assessed against auto analyzer.(12,13) This study found a high level of sensitivity, which suggests that digital hemoglobin meter Device A is effective at identifying individuals with anemia, making it suitable for screening purposes. However it has low specificity for detecting anemia, therefore shouldn't be used for the diagnostic purposes. The Lin's concordance correlation coefficient of 0.91 suggests strong agreement between the two methods, reinforcing the digital hemoglobinometer's reliability as a screening tool for anemia. The Bland-Altman analysis, supports the device's utility in resource-limited settings where access to advanced analyzers may be limited. Therefore in a resource limited setting or rural field area for the screening of anemia digital hemoglobin meter – Device A can be used. This study contributes valuable insights that may inform the adoption and integration of invasive digital hemoglobinometers as a routine tool for hemoglobin estimation in the field. These results can inform evidence-based decisions in maternal healthcare and contribute to improved antenatal care and anemia management. Additional research spanning diverse age groups, conducted in community settings, and involving frontline workers can further enhance the evidence base for validating digital hemoglobinometers.

The estimated device cost for the autoanalyzer was $ 9009, while the cost for the invasive digital hemoglobinometer DH was $142. The operating cost per test amounts to $0.36 for the autoanalyzer and $0.43 for the invasive DH. It's important to note that the operating cost of the invasive DH depends on the number of tests included in the package. The digital hemoglobinometer proves highly beneficial and user-friendly for hemoglobin detection. Its ease of cleaning the photometry/absorbance lens, responsible for assessing Hb levels, enhances its long-term functionality. Evaluating maintenance costs and assessing its practicality for use by frontline workers further contribute to its overall utility. The primary advantage of this device is that it features a rechargeable battery, a distinction from other digital hemoglobinometers that do not have rechargeable batteries. While operating the device, we encountered certain challenges. An issue observed while using the device is that it frequently enters sleep mode within 1-2 minutes, even when it is consistently connected to a power source through a charger or adapter. This recurring interruption can disrupt the workflow and efficiency of the device. The placement of the microcuvette inside the microcuvette holder is not seamless and lacks proper fitting. Consequently, when attempting to remove the microcuvette, it often results in the unintentional spillage of a few micro blood droplets. Another challenge encountered is the relatively prolonged duration required for drawing a blood droplet into the microcuvette through capillary action. This process takes approximately 4-7 seconds, which can be considered a longer time frame in certain operational contexts, potentially affecting overall efficiency. Addressing these challenges would be crucial for enhancing the usability and reliability of the device in its intended applications.

The study has several strengths, foremost among them being the meticulous adherence to quality control processes for the autoanalyzer and digital hemoglobinometer employed throughout the research. Furthermore, the consistent and careful collection of capillary and venous blood samples by a single trained laboratory technician, closely monitored throughout the process, adds to the robustness of the study.

CONCLUSION

The digital hemoglobinometer showed high sensitivity and diagnostic accuracy for anemia

detection in pregnant women, with substantial agreement with the hematology analyzer. It demonstrates a favorable level of agreement and concordance with the hematology autoanalyzer. This device can be used for anemia screening in resource-constrained settings, particularly where access to hematology autoanalyzer is restricted.

Limitation of the Study

The study did not assess the accuracy of digital hemoglobinometer when using venous blood, which precludes the ability to rule out potential differences between capillary and venous blood hemoglobin levels. Moreover, the results of the study may not be readily generalized to all healthcare workers of a facility or the field, as a skilled laboratory technician exclusively collected both types of blood samples at the healthcare facility and it was hospital based study. Additionally, the study did not evaluate the validity of the device in subgroups, such as those categorized by trimester or obstetric index, primarily due to the relatively small sample size within these subgroups.

Authors Contribution

All Authors have contributed equally.

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Nil

Conflict of Interest

There are no conflicts of interest.

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Declaration of Generative AI and AI Assisted Technologies in the Writing Process

During the preparation of this work Zotero software was used for citation management.

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