Section: Paediatrics

Original Research Article

ACCURACY OF NON-INVASIVE PULSE CO-OXIMETRY HEMOGLOBIN TESTING COMPARED WITH LABORATORY ANALYZER IN PEDIATRIC PATIENTS: A PROSPECTIVE STUDY AT A TERTIARY CARE CENTER

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ABSTRACT

Background: Anemia continues to pose a significant health burden among children in India, often necessitating prompt bedside evaluation. Traditional laboratory testing (venous sampling) involves procedural distress and logistical delays. **Objective:** To evaluate the accuracy and clinical agreement of non-invasive pulse co-oximetry (SpHb) compared with the gold-standard automated laboratory analyzer. **Materials and Methods:** A prospective observational study was conducted on 500 pediatric patients aged 1 month to 12 years at a tertiary care center. Simultaneous measurements of SpHb using pulse co-oximeter Masimo RAD-67 and venous hemoglobin was analyzed using a Sysmex automated hematology analyzer within 10 minutes. Data were analyzed using standard statistical software tools. Agreement between methods was assessed using Bland–Altman analysis. Diagnostic accuracy was evaluated using sensitivity, specificity, positive and negative predictive values. Receiver Operating Characteristic (ROC) curve analysis was performed to determine the discriminative ability of SpHb. A p-value of <0.05 was considered statistically significant. **Results:** The mean laboratory hemoglobin was 10.02 ± 1.74 g/dL, while mean SpHb was 10.88 ± 1.51 g/dL. The mean bias was +0.87 g/dL, with limits of agreement ranging from −2.13 to +3.86 g/dL. A moderate positive correlation was observed ($r = 0.563$, $p < 0.001$). For detection of anemia (Hb < 11 g/dL), sensitivity and specificity were 61.3% and 78.3%, respectively, with an AUC of 0.769. Sensitivity decreased significantly for moderate (38.3%) and severe anemia (17.9%), with a tendency of SpHb to overestimate hemoglobin at lower levels. Misclassification occurred in 52.3% of cases, with 82.1% of severe anemia cases underestimated. **Conclusion:** Non-invasive SpHb monitoring demonstrates moderate accuracy as a screening tool for anemia but has limited reliability in moderate to severe anemia due to overestimation. It may be useful for initial assessment and trend monitoring; however, confirmatory laboratory testing remains essential for clinical decision-making.

INTRODUCTION

Hemoglobin testing is a cornerstone of pediatric diagnostics, particularly in tertiary care centers like KGH where patients often present with advanced anemia.Globally, anemia remains a major public health concern, affecting an estimated 40% of children aged 6–59 months, according to the World Health Organization. The burden is disproportionately higher in low- and middle-income countries, with India contributing a significant share due to nutritional deficiencies, infections, and hemoglobinopathies. Early recognition is essential to prevent adverse outcomes, including impaired growth, developmental delay, and increased susceptibility to infections. In acute clinical scenarios, such as severe infections or hemoglobinopathies, timely identification of anemia plays a crucial role in guiding urgent management decisions.

Despite being the gold standard, laboratory-based hemoglobin estimation requires venous blood sampling, which can be distressing for children and may contribute to iatrogenic blood loss, especially in

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those requiring repeated monitoring. Additionally, the turnaround time for laboratory results may delay immediate clinical interventions in busy healthcare settings.

Non-invasive technologies, such as pulse co-oximetry (SpHb), have emerged as potential alternatives for rapid hemoglobin assessment. These devices provide real-time estimation using spectrophotometric principles without the need for blood sampling, making them particularly attractive in pediatric practice. The ability to obtain continuous and bedside measurements offers advantages in both outpatient and inpatient settings.

However, concerns remain regarding the accuracy and reliability of SpHb measurements, especially across different ranges of hemoglobin levels and clinical conditions. Factors such as peripheral perfusion, motion artifacts, and the presence of abnormal hemoglobin variants may influence device performance, potentially limiting its clinical applicability.

Given these considerations, it is important to evaluate whether non-invasive hemoglobin estimation can provide clinically acceptable agreement with standard laboratory methods. The present study was undertaken to assess the accuracy, agreement, and diagnostic performance of pulse co-oximetry (SpHb) compared with laboratory hemoglobin estimation in pediatric patients at a tertiary care center.

MATERIALS AND METHODS

Study Design: This was a prospective observational study conducted at Andhra Medical College/King George Hospital, Visakhapatnam, India.

Participants: 500 children aged 1 month to 12 years requiring routine CBC as part of their clinical care were enrolled using consecutive sampling.

Inclusion/Exclusion : Patients with parental consent were included. We excluded those in clinical shock, poor peripheral perfusion, or with conditions that would interfere with sensor accuracy (e.g., severe nail pigmentation or movement disorders).

Procedure:

Non-Invasive (SpHb): Measured using a pulse co-oximeter, Masimo RAD-67, Masimo corporation with an appropriately sized standard sensor applied to the fingertip or toe, and the reading was recorded once stable waveform was obtained.

Laboratory (Gold Standard): Within 10 minutes of the SpHb reading, a venous sample was processed via a Sysmex Automated Hematology Analyzer, which served as reference standard.

Statistical Analysis: Data were analyzed using standard statistical software tools. Continuous variables were expressed as mean ± standard deviation. Agreement between the two methods was assessed using Bland–Altman analysis. Correlation was evaluated using Pearson's correlation coefficient. Diagnostic accuracy was evaluated using sensitivity, specificity, positive predictive value, and negative predictive value at Hb thresholds anemia (<11 g/dL) , moderate anemia(Hb<10 g/dL), severe anemia (Hb<7g/dL). Receiver operating characteristic (ROC) curve analysis was performed to assess discriminative ability. A p-value of <0.05 was considered statistically significant.

Ethical Considerations

The study was initiated after receiving approval from the Institutional Ethics Committee (IEC) of Andhra Medical College. Written informed consent was obtained from all parents or legal guardians, and verbal assent was taken from older children. Patient confidentiality was strictly maintained by anonymizing all data sheets. As the procedures were part of standard clinical care, there was minimal additional risk to participants.

RESULTS

The study cohort included 500 pediatric patients.

Comparative Mean Values:

Laboratory Hb (Reference): 10.02 g/dL (SD ±1.74)

Pulse Ox Hb (SpHb): 10.88 g/dL (SD ±1.51)

Agreement Analysis: The mean bias was +0.87 g/dL, indicating that SpHb consistently overestimated the actual hemoglobin level.

Bland–Altman analysis showed Limits of Agreement (LoA) ranging from −2.13 g/dL to +3.86 g/dL. A total of 55.4% of readings were within ±1 g/dL 69.6% were within ±1.5 g/dL of laboratory hemoglobin values.

Diagnostic Performance:

Detection of Anemia (Hb < 11 g/dL):

Sensitivity	61.3%
Specificity	78.3%
PPV	85.8%
NPV	48.6%

Detection of Moderate Anemia (Hb < 10 g/dL):

Sensitivity	38.3%
Specificity	91.6%
PPV	76.7%
NPV	67.4%

Detection of Severe Anemia (Hb < 7 g/dL):

Sensitivity	17.9%
Specificity	100%
PPV	100%
NPV	95.3%

SpHb showed significantly reduced sensitivity in detecting severe anemia, with a tendency to overestimate hemoglobin in lower ranges.

Misclassification Analysis:

47.7% of patients were correctly classified, while 52.3% were misclassified by at least one anemia severity category. Notably, 82.1% of severe anemia cases (Hb < 7 g/dL) were underestimated by SpHb.Misclassification was more frequent at lower hemoglobin levels, while accuracy improved in normal to mild anemia ranges.

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Correlation Analysis

The Pearson correlation coefficient (r) was 0.563 ($p < 0.001$), indicating a moderate positive linear relationship between SpHb and laboratory Hb values.

ROC Analysis

Receiver Operating Characteristic (ROC) analysis showed an Area Under the Curve (AUC) of 0.769, indicating good diagnostic accuracy for detecting anemia.

Bland–Altman Interpretation

The Bland–Altman plot demonstrated a mean bias of +0.87 g/dL with wide limits of agreement (−2.13 to +3.86 g/dL). The variability increased at lower hemoglobin levels, indicating reduced agreement in moderate to severe anemia.

DISCUSSION

This study evaluated the clinical utility of non-invasive pulse co-oximetry (SpHb) in comparison with standard laboratory hemoglobin estimation in a pediatric population. The findings demonstrate that while SpHb shows a statistically significant association with laboratory hemoglobin values, its clinical applicability is limited by moderate agreement and systematic overestimation.

The mean bias of +0.87 g/dL observed in this study aligns with previous literature, indicating a tendency of SpHb devices to overestimate hemoglobin values. Although the correlation coefficient ($r = 0.563$) reflects a moderate linear relationship, a linear relationship between two methods does not necessarily indicate clinical equivalence, as highlighted by the wide limits of agreement (−2.13 to +3.86 g/dL). The observed variability restricts the use of SpHb as a direct substitute for laboratory hemoglobin estimation.

The diagnostic performance analysis further emphasizes these limitations. While SpHb demonstrates reasonable sensitivity (61.3%) and specificity (78.3%) for detecting anemia, its performance declines considerably with increasing severity. Sensitivity dropped to 38.3% for moderate anemia and 17.9% for severe anemia. Missing cases of severe anemia can potentially postpone critical therapeutic interventions.The high specificity (100%) and positive predictive value for severe anemia suggest that positive readings are reliable; however, the device fails to identify a significant proportion of affected patients. This is further supported by misclassification findings, where over 52% of cases were incorrectly categorized, and 82.1% of severe anemia cases were underestimated. Such underestimation limits its role in high-risk clinical situations.

The increased variability at lower hemoglobin levels observed in Bland–Altman analysis may be due to altered peripheral perfusion, motion artifacts, and the presence of hemoglobin variants. Such influences are especially significant in pediatric clinical settings and in conditions like thalassemia and sickle cell disease.

Despite these limitations, SpHb offers clear advantages, including non-invasive measurement, rapid results, and the ability to provide continuous monitoring. These characteristics make it a useful adjunct in screening and trend monitoring, particularly in high-volume or resource-limited settings.

Therefore, reliance on SpHb alone in clinically suspected moderate to severe anemia may lead to underdiagnosis and delay in timely intervention.

Strengths and Limitations:

This study included a large pediatric sample and evaluated device performance across different anemia severities, enhancing its clinical applicability. However, it is limited by its single-center design and potential influence of physiological and technical factors affecting SpHb accuracy.

CONCLUSION

Non-invasive pulse co-oximetry (SpHb) is a useful bedside screening tool for rapid hemoglobin assessment in pediatric patients. It demonstrates moderate diagnostic accuracy for detecting anemia but has limited reliability in moderate to severe anemia due to consistent overestimation.

While SpHb is valuable for initial screening and monitoring trends, it cannot be considered a replacement for standard laboratory hemoglobin measurement. Laboratory confirmation remains mandatory, particularly when critical decisions such as blood transfusion are being considered.

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