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CLINICAL RESEARCH ARTICLE

Evaluation of the use of non-invasive hemoglobin measurement in early childhood

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BACKGROUND: Iron deficiency anemia in children affects psychomotor development. We compared the accuracy and trend of a non-invasive transcutaneous spectrophotometric estimation of arterial hemoglobin (Hb) concentration (SpHb) by rainbow pulse CO-oximetry technology to the invasive blood Hb concentration measured by an automated clinical analyzer (Hb-Lab).
METHODS: We measured the SpHb and Hb-Lab in 109 patients aged 1–5 years. Regression analysis was used to evaluate differences between the two methods. The bias, accuracy, precision, and limits of agreement of SpHb compared with Hb-Lab were calculated using the Bland–Altman method.
RESULTS: Of the 109 enrolled subjects, 102 pairs of the SpHb and Hb-Lab datasets were collected. The average value of measured Hb was 12.9 ± 1.03 (standard deviation [SD]) g/dL for Hb-Lab. A significant correlation was observed between SpHb and Hb-Lab measurements (SpHb = 7.002 + 0.4722 Hb-Lab, correlation coefficient $r = 0.548$, 95% confidence interval = 0.329–0.615). Bland–Altman analysis showed good visual agreement, with a mean bias between SpHb and Hb-Lab of 0.188 ± 0.919 g/dL (mean ± SD).
CONCLUSIONS: We concluded that non-invasive Hb measurement is useful for Hb estimation in children and provides new insights as a screening tool for anemia.

Pediatric Research (2023) 93:1036–1040; https://doi.org/10.1038/s41390-022-02204-7

IMPACT:

- Our results indicated a good correlation between non-invasive transcutaneous spectrophotometric estimation of arterial hemoglobin (Hb) concentration using a finger probe sensor by rainbow pulse CO-oximetry technology and invasive blood Hb concentration.
- Although previous studies have indicated that in patients with a worse condition, the bias between the two methods was large, this study, which was conducted on children with stable disease, showed a relatively small bias.
- Further studies using this non-invasive device might help to understand the current status of anemia in Japan and promote iron intake and nutritional management in children.

INTRODUCTION

Anemia is characterized by a decreased quantity of red blood cells, often accompanied by diminished hemoglobin (Hb) levels or altered red blood cell morphology.[1] Iron deficiency and iron-deficiency anemia continue to be a concern worldwide,[2] and anemia remains one of the most serious public health problems. Recent estimates by the World Health Organization (WHO) indicate that in 2011, the highest prevalence of anemia was observed in children (42.6%, 95% confidence interval [CI]: 37–47).[3]

It has been suggested that the consumption of iron-fortified foods significantly increases Hb concentration in children aged <10 years.[4] Iron intake in Japan is lower than that in other developed countries.[5] The National Health and Nutrition Examination Survey in 2016 indicated that the iron intake for Japanese children was 3.5 mg/day for those aged 1–2 years and 4.3 mg/day for those aged 3–5 years.[6] In 2020, the recommended intake of iron was 4.5 mg/day (for 1–2 years of age) and is 5.5 mg/day (for 3–5 years of age).[7] However, it was determined that the recommended dietary intake of iron for 1–3 years of age is 7 mg/day in United States,[2,8] and the fact that children actually consume more than the recommended amount of iron shows the low level of iron intake of Japanese children. In other countries, a correlation between iron intake in children and the prevalence of anemia has been suggested.[9] In 2019, World Bank reported a 16.7% prevalence of anemia among Japanese children aged 6–59 months.[10]

Iron deficiency in children negatively affects a variety of neurodevelopmental processes at the time of nutrient insufficiency, with persistent central nervous system alterations and deficits in behavioral functioning, despite iron therapy.[11] It affects psychomotor development, including decreased intelligence and attention and abnormalities in motor, cognitive, and neurobehavior, some of

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Received: 27 February 2022 Revised: 2 June 2022 Accepted: 7 June 2022
Published online: 29 July 2022

which are irreversible. While prevention of iron deficiency is of utmost importance, early detection of anemia and intervention, including dietary assessment, is necessary.

Hb assessments are widely used to screen individuals for anemia, draw inferences about the iron status of populations, and evaluate responses to nutritional interventions.[12] Determination of Hb concentration for anemia assessment is among the most frequently performed laboratory tests in in- and outpatient care.[13] This is mainly assessed by blood tests; however, invasive procedures are required for blood collection. It not only causes pain and discomfort to the patient and parents but also has the potential to induce iatrogenic anemia.

Recently, it has been reported that the estimate of Hb concentration using non-invasive pulse CO-oximetry shows good global correlation with Hb concentration using a core lab analyzer.[14] The Rad-67™ Pulse CO-Oximeter® with a rainbow® Super DCI®-mini sensor (Masimo Corporation, Irvine, CA) is a new device that provides a continuous, non-invasive measurement of Hb concentration (SpHb) in arterial blood. We evaluated the tendency and accuracy of SpHb using this device by comparing the Hb concentration obtained with an automated laboratory analyzer (Hb-Lab) in children. Then, we examined whether non-invasive Hb measurements could be used for anemia screening in future.

MATERIALS AND METHODS

Study population

This prospective comparative study was conducted from January 2020 to December 2021 in pediatric out- and inpatients at Juntendo University Hospital who were scheduled for blood tests. After approval from the Ethics Committee of Juntendo University Hospital (approval number: 20-056), informed consent was obtained from each patient's guardian before enrollment. Hb levels of 109 patients aged 1–5 years were enrolled. Patients were excluded from the study if they had congenital heart disease (excluding cases of hemodynamic normalization with treatment), hematologic oncologic disease (excluding after treatment of solid tumors), acute phase of infection or vasculitis syndrome, and chronic kidney disease. Patient demographics, including sex, age, birth history, and disease type were collected. Basic patient data, such as weeks of gestation, birth weight, and height were also recorded.

Hemoglobin measurement

Hb levels were measured in two ways: SpHb and Hb-Lab levels. For SpHb testing, a pulse CO-oximeter finger probe sensor (Masimo Rad-67™ Pulse CO-Oximeter® with Rainbow ® Super DCI®-mini Sensor) was attached to the middle finger or thumb of the dominant hand. As per the Masimo rainbow set rad-67 pulse co-oximeter's operator's manual, rainbow pulse CO-oximetry technology is governed by the following principles: oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin), and blood plasma constituents differ in their absorption of visible and infrared light (spectrophotometry). The amount of arterial blood in the tissue changes with the pulse (photoplethysmography). Therefore, the amount of light absorbed by varying quantities of arterial blood also changes. Rad-67 uses a multiwavelength sensor to distinguish between oxygenated and deoxygenated blood, blood with carbon monoxide, oxidized blood, and blood plasma. Rad-67 utilizes a sensor with various light-emitting diodes (LEDs) that pass light through a site to a diode (detector). Signal data are obtained by passing various visible and infrared lights (LEDs, 500–1400 nm) through a capillary bed (for example, a fingertip, hand, and foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful for clinicians. The maximum radiant power of the strongest light source was rated at ≤25 mW. The detector receives light, converts it into an electronic signal, and sends it to Rad-67 for calculation. Once Rad-67 receives a signal from the sensor, it utilizes proprietary algorithms to calculate the patient's functional oxygen saturation (SpO_2 [%]), total hemoglobin concentration (SpHb [g/dL]), and pulse rate (PR).[15] This measurement was performed twice, and the average of the two values was used as the true SpHb. If the difference between the two measurements of SpHb was >1 g/dL, a third measurement was taken, and the average of the two closest values was used. If SpHb could not be recorded within 5 min, the patient was considered difficult to examine.

For venous sampling, 2 ml of blood was collected in Vacutainer tubes containing potassium ethylenediaminetetraacetic acid as an anticoagulant. The contents were thoroughly mixed, and then sent immediately to the central lab at Juntendo University Hospital for analysis. Hb levels were measured using a standard automated analyzer (Sysmex XE-5000, Kobe, Japan). Iron and ferritin levels were also measured as parameters related to anemia.

Statistical analysis

GraphPad Software Prism version 9.3.0 was utilized for statistical analysis. The concordance between the two methods of SpHb and Hb-Lab was confirmed by the paired *t*-test and the simple linear regression. The Bland–Altman procedure plot was used to evaluate agreement. The mean, SD, 95% CIs and ranges of the difference, and the 95% limits of agreement (LOA) were calculated. Based on previous studies, bias above 1.5 g/dL was adopted as the cut off value.[16,17]

RESULTS

Of the 109 subjects enrolled, 102 pairs of SpHb and Hb-Lab datasets were collected and analyzed. The results of seven patients with only one SpHb value were excluded. SpHb for five children was measured thrice because the difference between the two measurements of SpHb was more than 1.0 g/dL. A total of 49 patients were male and 53 were female, ranging in age from 1 to 5 years, with an average age of 3.698 years. There were 54 infants (1–3 years) and 48 children (4–5 years). The characteristics of the subjects and procedures are shown in Table 1. Among eligible patients, the follow up clinic with history of prematurity was the largest at 24%. The others were food allergies (14%), short stature (9%), and hypothyroidism (9%), with little bias in the diseases (Table 2). Among the 24 preterm follow up patients, 19 had a very low birth weight, while the others mainly had preterm delivery or fetal growth arrest.

The average values of measured Hb were 13.1 ± 0.89 (SD) g/dL for SpHb and 12.9 ± 1.03 (SD) g/dL for Hb-Lab. A total of four patients were severely anemic with Hb-Lab ≤11 g/dL and ferritin values 12 ± 7 (SD) ng/mL. Figure 1 plots the SpHb and Hb-Lab measurements with a regression line (SpHb = 7.002 + 0.4722 Hb-Lab, correlation coefficient $r = 0.548$, 95% CI = 0.329–0.615). SpHb and Hb-Lab showed a significant positive correlation; however, SpHb was overestimated when Hb-Lab was above 13.3 g/dL and underestimated when Hb-Lab was below 13.3 g/dL.

The agreement between the two methods was confirmed using Bland–Altman plots with 95% values (Fig. 2). These methods of SpHb and Hb-Lab had similar results on average. The mean bias was 0.188 and the SD of the bias was 0.919 g/dL. The 95% LOA were between −1.613 and 1.988 g/dL. The difference between SpHb and Hb-Lab was within 1.0 g/dL in 75.0% and within 1.5 g/dL in 87.3% patients.

Table 1. Patient demographics.

Subjects	***n* = 102**
Sex (Male/Female)	49/53
Age range	
- 1 y	11
- 2–3 y	43
- 4–5 y	48
Birth history	
- LBW infant	38
- VLBW infant	19

Table 2. Classification of main disease and SpHb, Hb-Lab in patients.

Classification	Main disease (number of patients)	SpHb (g/dL)	Hb-Lab (g/dL)
Follow up clinic	Preterm and low birth weight babies (24)	13.2 ± 0.92 (SD)	13.3 ± 0.75 (SD)
Chromosomal abnormality malformative syndrome	21 trisomy (3)	12.3 ± 2.07 (SD)	12.0 ± 2.08 (SD)
	22q11.2 deletion syndrome (1)		
	Beckwith–Wiedemann syndrome (1)		
Metabolic and endocrine diseases	Hypothyroidism (9)	13.0 ± 0.71 (SD)	13.3 ± 0.79 (SD)
	Short stature (9)		
	Type 1 diabetes mellitus (3)		
	21 Hydroxylase deficiency (1)		
	Premature thelarche (1)		
Cardiac diseases	Paroxysmal supraventricular tachycardia (1)	13.8 ± 0.23 (SD)	13.1 ± 0.20 (SD)
	Atrial septal defects (1)		
Hepatobiliary diseases	Biliary atresia (2)	13.5 ± 0.42 (SD)	13.2 ± 0.80 (SD)
	Biliary dilatation (1)		
	Unexplained cholestasia (1)		
	Neonatal intrahepatic cholestasis caused by citrin deficiency (1)		
	Intrahepatic portosystemic shunt (1)		
Allergy and autoimmune diseases	Food allergy (14)	12.9 ± 0.68 (SD)	13.4 ± 0.74 (SD)
	Mucocutaneous lymph-node syndrome (2)		
	Food protein induced enterocolitis syndrome (1)		
	IgA vasculitis (1)		
Renal and urological diseases	Nephrotic syndrome (2)	13.1 ± 0.77 (SD)	12.8 ± 0.82 (SD)
	Multicystic dysplastic kidney (2)		
	Posterior urethral valves (1)		
	Vesicoureteral reflux (1)		
	Hydronephrosis (1)		
Gastrointestinal diseases	Inflammatory bowel disease (3)	12.2 ± 0.87 (SD)	11.6 ± 1.45 (SD)
	Small bowel hemorrhage (1)		
	Inguinal hernia (1)		
Blood and tumor diseases	Idiopathic thrombocytopenic purpura (2)	13.1 ± 0.65 (SD)	12.5 ± 0.42 (SD)
	Unexplained Thrombocytopenia (1)		
	Astrocytoma (1)		
	Yolk sac tumor (1)		
	Rhabdomyosarcoma (1)		
Neuromuscular diseases	Epilepsy (1)	14.0 ± 1.20 (SD)	13.4 ± 0.05 (SD)
	Myasthenia gravis (1)		
Others	Scurvy (1)	13.1 ± 0.41 (SD)	12.5 ± 0.48 (SD)
	FGF23-mediated hypophosphatemic rickets (1)		
	Vitamin D deficiency rickets (1)		
	Lymphadenopathy (1)		

DISCUSSION

This study showed a good correlation between non-invasive SpHb and invasive Hb-Lab measurements. This result can be adapted clinically; however, the 12.7% disagreement in SpHb should be considered when the cut-off value for bias is set at 1.5 g/dL or higher. This trend is equivalent to the previously reported mean bias of −0.6 ± 1.1 g/dL between SpHb and Hb-Lab in healthy children.[18] Non-invasive Hb values measured with the Pronto® device with DCI-mini™ sensors (Masimo Corporation, Irvine, CA) were significantly positively correlated with venous Hb levels (correlation coefficient, $r = 0.43$, $p < 0.0001$) in children 6–59 months of age with moderate strength.[19] In addition, in 52 neonates ⩽32 weeks of gestation (144 paired samples), the correlation coefficient of total Hb versus SpHb was moderately positive ($r = 0.69$, $p < 0.001$).[20]

It has been reported from other countries that non-invasive Hb measurement allows for continuous monitoring of anemia and reduction of unnecessary blood transfusions in acute and perioperative patients.[14,17,21] In one study, they also found that the difference in Hb estimation by SpHb and Hb-Lab was significantly higher in subjects with shock than that in healthy subjects (−2.31 ± 2.21 g/dL versus −0.77 ± 1.2 g/dL).[17] In addition, a previous meta-analysis reported the overall pooled random effects mean difference (non-invasive - central laboratory) and SD as 0.10 ± 1.37 g/dL (95% LOA = −2.59 to 2.80 g/dL, $I^2 = 95.9\%$ for mean difference and 95.0% for SD).[22] Of the 32 studies included in

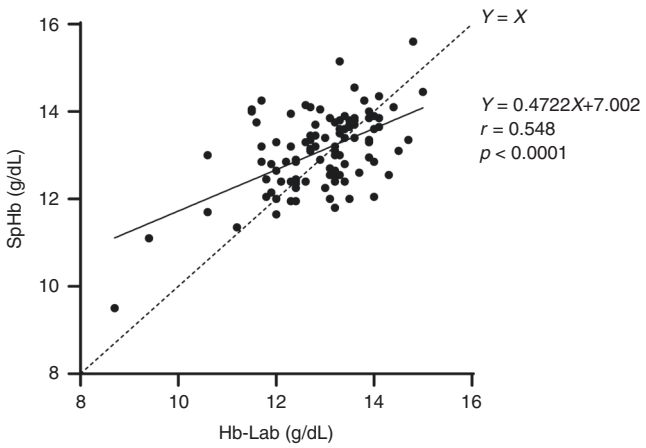

Fig. 1 Correlation chart between SpHb and Hb-Lab. The two measurements showed a significant positive correlation. The solid line is the line of regression, and the dotted line is a straight line assuming the same values for SpHb and Hb-Lab. The two lines intersect when SpHb and Hb-Lab were 13.3 g/dL.

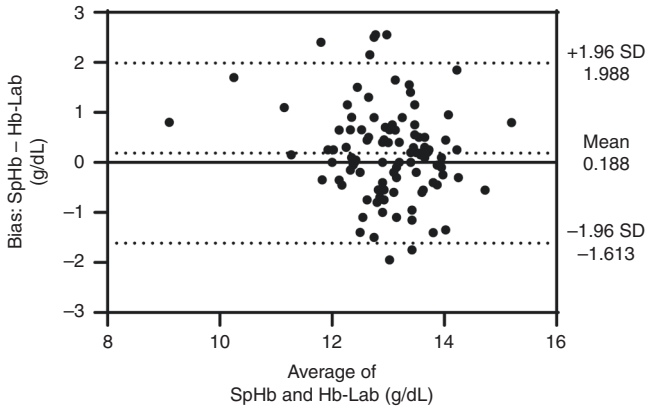

Fig. 2 Bland–Altman plot of SpHb and Hb-Lab ($n = 102$). Dotted lines indicated the mean bias and 95% LOA. The mean bias was 0.188 ± 0.919 g/dL (SD) and the 95% LOA were −1.613 to 1.988 g/dL. The solid line indicated a bias of ±1.5 g/dL.

the meta-analysis, 17 had been conducted in the perioperative and critical care settings. In the present study, the 95% LOA were between −1.613 and 1.988 g/dL with respect to bias of the two measurement methods. Considering the possibility of over or under-estimation of Hb, the data should be interpreted with caution. Previous studies have shown that in patients with worse conditions, the bias between the two methods may be large due to circulatory failure, but in healthy patients, including children, the bias is relatively small. This study was intended for use in screening and we did not measure Hb trends in critically ill patients, such as acute, perioperative, or PICU management, rather measured Hb levels in children with stable disease. It is not necessarily an accurate representation of the healthy Japanese child population; however, the purpose of hospital visits varies, and there is no disease bias in the population.

This study has some limitations. In 2002, a study conducted in Iwate, Japan reported the mean ± SD of Hb levels as 11.3 ± 1.2 g/dL in children aged 6–18 months; 8% of the children were diagnosed as anemic.[23] Globally, the mean blood Hb concentration is 11.1 g/dL (95% CI: 110–113) in children.[3] Approximately 12% of infants aged 6–11 months in the United States have inadequate iron intake, and 8% of toddlers have iron deficiency.[24,25] In the present study, 4% children were found to be significantly anemic (Hb ≤ 11 g/dL). The results were based on data from a single hospital. As iron deficiency is often caused by nutritional deficiencies and lack of nutritional management, the patient's and his/her family's background and standard of living should be considered. To determine whether non-invasive Hb measurements could be used for anemia screening, it may be worthwhile to accumulate a number of cases of anemic children in multiple hospitals and institutions in a larger region. Further expansion of the age range, especially for children under 1 year of age who are prone to iron deficiency, will lead to a better understanding of the actual status of anemia in Japanese children.

It is difficult to diagnose anemia in healthy children based on appearance, history, and physical examination. In future, non-invasive screening for anemia without blood sampling could be possible in general pediatric clinics and child health checkups. As mentioned above, the iron intake of Japanese children is low compared to that of children in other developed countries. Consequently, further studies using this non-invasive device might help diagnose anemia in more children in Japan than ever before. The recommended iron intake in Japan is also lower than that in other countries;[7,8] therefore, it is important to review the nutritional guidelines, including the recommended amounts of each nutrient.

CONCLUSIONS

We conclude that non-invasive Hb measurement is useful for Hb estimation in children. The present study explores the possibility of using non-invasive Hb measurement as a screening tool for anemia. Therefore, further studies should be conducted on anemic children in order to confirm the use of non-invasive Hb measurement as a screening tool. If non-invasive Hb measurement could be used for screening, it would help to understand the current status of anemia in Japan and promote iron intake and nutritional management in children.

DATA AVAILABILITY

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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ACKNOWLEDGEMENTS

We would like to thank the Pediatrics and Pediatric Surgery Team at Juntendo University Hospital for their help and collaboration in conducting this study. We would like to thank Editage (www.editage.com) for English language editing.

AUTHOR CONTRIBUTIONS

H.S. and T.I. contributed to the conception and design of this study. Y.A. and K.A. Acquired patients' data. Y.A. and H.S. performed the statistical analysis and interpretation of data, drafted the manuscript. E.I. and T.S. Revised manuscript critically for important intellectual content. All authors read and approved the final manuscript.

FUNDING

This work was financially supported by Meiji Co., Ltd.

COMPETING INTERESTS

The authors declare no competing interests.

CONSENT TO PARTICIPATE

Informed consent was obtained from each patient's guardian before enrollment.

ADDITIONAL INFORMATION

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