A Cross–Sectional Study on Validity of Digital Hemoglobinometer in Estimating the Haemoglobin Level among Government School Children in Virudhunagar City, Tamil Nadu

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Abstract:

Introduction: Anemia is a significant public health concern, particularly among adolescents. With more than half of all adolescents living in Asia and a substantial portion in India, where adolescents make up 21% of the population, addressing anemia in this age group is vital. **Objectives:** 1.To estimate the validity of screening tool digital hemoglobinometer against the gold standard method automated analyser, 2. To estimate the prevalence of anemia among the Government middle school children in Virudhunagar district using automated analyser. **Method:** This cross-sectional study was conducted over a three-month period from March to May 2023 and included 357 students from government schools in Virudhunagar. Cluster random sampling was employed to select representative schools, and a semi-structured questionnaire was used to collect demographic data and information on risk factors. Haemoglobin levels were measured using both the digital hemoglobinometer and the automated analyzer. Sensitivity, specificity, positive predictive value, and negative predictive value were calculated to assess the validity of the digital hemoglobinometer. **Results:** The study revealed that the digital hemoglobinometer had a sensitivity of 75.64% and a specificity of 76.70% when compared to the automated analyzer. While there was a statistically significant difference between the two methods, the digital hemoglobinometer demonstrated its effectiveness as a screening tool, particularly for identifying cases of moderate and severe anemia. The study suggests that in resource-limited settings, the digital hemoglobinometer could play a crucial role in early detection and intervention for anemia among school children. **Conclusion:** These findings underscore the potential of accessible digital hemoglobinometers in school health programs, where advanced laboratory equipment may not be readily available. The study also highlights the need for further research with larger sample sizes and diverse digital hemoglobinometer types to refine and expand the use of this technology in addressing anemia in school-aged children.

Keywords: Medical Students, Smoking, Tobacco

Introduction:

Anemia is an important public health problem. According to the World Health Organization (WHO), anemia is defined as having hemoglobin (Hb) levels lower than 12.0 g/dl in females and 13.0 g/dL in males.[1] Oxygen is carried by Haemoglobin so in anaemia there will be decreased capacity of the blood to carry oxygen to the body tissues resulting in fatigue, weakness, dizziness and shortness of breath. In India Adolescents constitute 21% of the countrys population.[2] Anemia at this stage in life has long-term impact over their health, like developmental problems, cognitive functioning, school

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performance, decreased immunity, irregular menstrual cycles, poor pregnancy effects like maternal morbidity and mortality, preterm delivery, low birth weight, and perinatal mortality infants born to anemic mothers have a greater risk of anemia in the first six months of life.[3-5] Iron deficiency, folate, and vitamin B12 deficiency are the most common cause of anemia.[6]

According to NFHS -5, in all over India, showed an upward trend in the prevalence of anemia among girls of 15-19 years - 59% (NFHS-4 -54%) and among boys of 15-19 years- 31% (NFHS-4 -29.2%). The prevalence of severe anemia among them was 2.6% and 0.3%, respectively.[7] Comprehensive National Nutrition Survey (CNNS) 20162018 done on Indian adolescents found that 28.5% of adolescents (girls: 39.6%, boys: 17.6%) were anemic and the major causes of anemia were vitamin B12 deficiency (25.6%), Iron deficiency (21.3%), dimorphic anemia (18.2%), anemia of inflammation (3.4%).[8] Various studies conducted among adolescents in various parts of India showed that the prevalence of anemia was 61.5% in Gujarat, 52.5% in Madhya Pradesh, 41.1% in Karnataka, 50% in Bihar and 56.5% in Uttar Pradesh, 88.6% in Tamilnadu (Coimbatore).[9-13]

The National Nutritional Anemia Prophylaxis program was initiated in 1970 to prevent anemia mainly targeting children and pregnant mothers. Later on, various programs like the weekly iron-folic acid supplementation (WIFS) program and the Anaemia Mukth Bharath program were initiated for the supplementation of iron tablets prophylactically to prevent anemia in adolescents. In spite of these programs, the prevalence of anemia showed an upward trend. Hence need for screening tools to measure the overall burden among adolescents. Even though, an automated analyser is a gold standard tool to measure hemoglobin level, a digital hemoglobinometer is simple and easily available, so it could be used for screening at the field level. Sahlis hemoglobinometer which is used as a current screening tool has some limitations like the chance of visual error, the color of glass standard may fade over time and it cant measure all the hemoglobins. Hence the need for this study to screen anemia and to find the burden of anemia among government middle school children in Virudhunagar district using a screening tool against the gold standard method and to estimate the validity of the digital hemoglobinometer.

Objectives:

1 To estimate the validity of screening tool digital hemoglobinometer against the gold standard method automated analyser.

2. To estimate the prevalence of anemia among the Government middle school children in Virudhunagar district using automated analyser.

Method:

A cross-sectional study was carried out in government schools in Virudhunagar among adolescents of class 6 to 8. The study duration was three months from March 2023 to May 2023. A study done by Shanmugam et al in Coimbatore, Tamil Nadu found that the prevalence of anemia among adolescents was 88.6%,[13] so the q value is 11.4, keeping absolute precision as 5% and design effect 2 sample size calculated using the formula $4pq/L^2$ was 310 and by taking non-response rate as 20% final sample size calculated was 372. Cluster random sampling technique was used. All the homogenous schools in terms of proportion of students in different standards, girls & boys composition were selected. Schools with students strength of 80 and above were considered. There were totally 20 such homogenous schools. Each school was considered as a cluster. Estimated sample size was 372 and minimal strength in each school was 80. So number of clusters to be selected was calculated based on the formula;[14] estimated sample size/number of students in each cluster = 372/80 = 4.65. So approximately 5 clusters were selected randomly from the 20 homogenous clusters and all the students in those school clusters were included in the study. Total strength of five schools was 507, after applying the exclusion criteria

the final sample size arrived was 357. Non-co-operative children, those who were absent during the time of data collection, those who were suffering from any chronic medical illness were excluded from the study.

Predesigned semi-structured questionnaire was used to collect the basic demographic data and data regarding other risk factors of anemia. As per WHO expert group guidelines hemoglobin less than 12 g/dl was considered to be anemic for children from 6 to 14 years Institutional ethical clearance was obtained. Informed consent was got from the parents or guardian. The confidentiality of the participants was maintained through-out the study Prior permission was got from the school authority. After getting consent, data was collected by the trained persons. Blood sample was collected and Hemoglobin was estimated using both the methods. Data were entered in Microsoft excel and SPSS version 16 was used for analysis. Descriptive statistics was used to find frequencies and percentages. Kappa statistics along with agreement analysis and independent sample t test was used for comparison between the readings of both the tools used. Sensitivity, specificity, positive predictive value and negative predictive value were calculated.

Sensitivity is percentage of true positives among the diseased (as estimated by automated analyser). Specificity is percentage of true negatives among the non-diseased (as estimated by automated analyser). Positive predictive value is the percentage of true positives among the total positives (as estimated by digital hemoglobinometer). Negative predictive value is the percentage of true negatives among the total negatives (as estimated by digital hemoglobinometer).[15]

Cohens Kappa was calculated using the below formula and interpretation was as follows [16]

Pr(a)-Pr(e) / 1- Pr(e)

Pr(a) is observed agreement and Pr(e) is expected agreement

Interpretation for Cohens Kappa: 0 no agreement, 0.10 0.20 slight agreement, 0.21 0.40 fair agreement, 0.41 0.60 moderate agreement, 0.61 0.80 substantial agreement, 0.81 0.99 near perfect, 1 perfect agreement

Results:

Out of 357 students included in the study 50.4% were males and 49.6% were females. The majority of them (40.1%) were of 13 years old. Table 1 show the age and sex distribution of the study population.

Table 1: Age and Gender distribution of the study population (N= 357)

Age in years	Gender		Total
	Female n(%)	Male n(%)	
10	2 (0.6%)	0 (0%)	2 (0.6%)
11	20 (5.6%)	48 (13.4%)	68 (19.0%)
12	65 (18.2%)	49 (13.7%)	114 (31.9%)
13	72 (20.2%)	71 (19.9%)	143 (40.1%)
14	21 (5.9%)	9 (2.5%)	30 (8.4%)
Total	180 (50.4%)	177 (49.6%)	357 (100.0%)

The prevalence of anemia as estimated by the gold standard automated analyser and digital hemoglobinometer are 21.8% (Figure 1) and 34.7%, (Figure 2) respectively. Total 14.2% were mild anemic, 5.3% were moderately anemic and 2.3% were severely anemic as estimated by automated analyser. 21.4% were mild anemic,9.5% were moderately anemic and 3.8 % were severely anemic.

Figure 1: Prevalence of Anemia as Estimated by Automated Analyser (N=357)

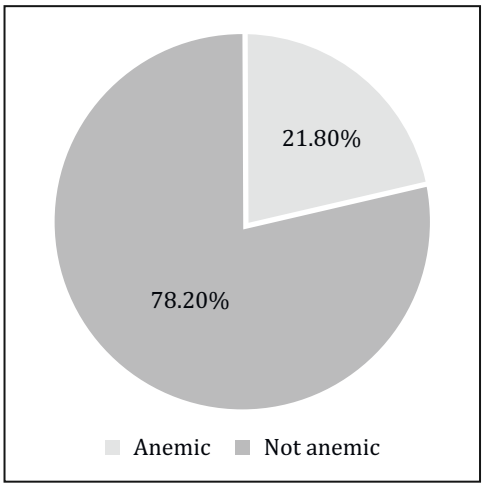

Figure: 2 Prevalence of anemia as estimated by digital hemoglobinometer (N=357)

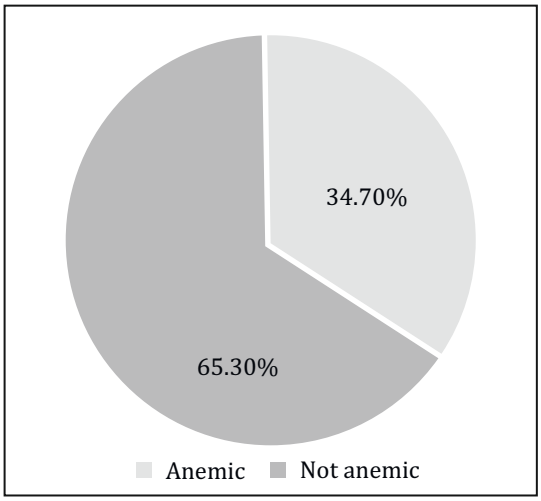

Table 3 shows independent sample t test between hemoglobin recorded by two device p value was 0.08 showing that there is no statistically significant difference between hemoglobin recorded by two devices.

By comparing between the anemia diagnosed by screening tool, digital hemoglobinometer and gold standard automated analysesensitivity was 75.641%, specificity was 76.702%, positive predictive value was 47.5% and negative predictive value was 91.8%. (Table 4)

Pr(a) is total true positives and negatives among total screened .273 were correctly diagnosed by the screening tool among 357 screened so Pr(a) is 273/357 that is 0.76

Table 2: Categorization of Anemia by Automated Analyser versus Digital Hemoglobinometer (n = 357)

Anemia by digital hemoglobinometer	Diagnosis of Anemia by Automated Analyser				
	Non-anemic n(%)	Mild n(%)	Moderate n(%)	Severe n(%)	Total n(%)
Non-anemic	214 (91.8%)	19 (8.2%)	0	0	233 (100%)
Mild	44 (57.1%)	32 (41.6%)	1 (1.3%)	0	77 (100%)
Moderate	16 (47%)	0	16(47%)	2 (6 %)	34(100%)
Severe	5(38.5%)	0	2(15.4%)	6 (46.1%)	13(100%)
Total	279 (78.2%)	51(14.3%)	19(5.3%)	8(2.2%)	357(100%)
% of agreement for mild anemia 82.07% with Cohens K 0.388 = Fair agreement % of agreement for moderate anemia 94.11% with Cohens K 0.57 = Moderate agreement % of agreement for severe anemia 97.47% with Cohens K 0.56 = Moderate agreement					

Table 3: Mean hemoglobin values estimated by two devices (n = 357)

Device	Mean	Standard Deviation	Standard Deviation difference	Mean difference	T value	P Value
Digital hemoglobinometer	11.44	1.23	0.11	0.15	- 1.7032	0.08
Automated analyser	11.59	1.12				

Table 4: Validity of Screening tool versus gold standard test

Digital hemoglobinometer	Automated analyser		Total
	Positive	Negative	
Positive	True positive (a) = 59	False positive (b)= 65	124
Negative	False negative (c) =19	True negative(d) =214	233
Total	78	279	357
% of agreement for diagnosis of anemia 76.47% with Cohens K 0.43 = Moderate agreement			

Pr (e) is (a +b / n Xa+c/n) + (c+d/n X b+d /n)

(124/357 X 78/357) + (233/357 X 279/357) = 0.59

Cohens K 0.76-0.59/0.4 = 0.43 = Moderate agreement

Discussion:

The Prevalence of anemia as estimated by the gold standard automated analyser was 21.8%. The prevalence of anemia as estimated by the digital hemoglobinometer was 34.7%. this was comparatively lower than the pooled prevalence of Indian adolescence estimated in a systemic review and meta-analysis done by estimated by Daniel et al.[17]

The mean hemoglobin estimated by the digital hemoglobinometer was 11.44 g/dl. Mean hemoglobin estimated by the automated analyzer was 11.59 g/dl. Prevalences is comparatively less and mean hemoglobin estimated by both digital hemoglobinometer and automated analyser were comparatively more than in an another study done by Yadav K et al[18] (hemoglobinometer A - prevalence of anemia 55% ,mean Hb 10.9g/dl, hemoglobinometer B - prevalence of anemia 58% ,mean Hb 10.8 g/dl, Automated analyser - prevalence of anemia 57%,meanHb 10.8 g/dl)and Toppo et al[19](hemoglobinometer- mean Hb 9.89 g/dl,Automated analyser - mean Hb -10.19 g/dl).

In the present study female gender and 8th standard were significantly associated with anemia. The sensitivity of digital hemoglobinometer was 75.641 %, specificity was 76.702 %,positive predictive value was 47.5% and negative predictive value was 91.8 %. This is in contradictory to other studies. Study done by Toppo M. et al [19]in assessing the validity of digital hemoglobinometers compared to, automated analyser shows that Overall, sensitivity of Digital Hemoglobinometer for hemoglobin estimation was calculated to be 89.4% and specificity was calculated to be 63.6 % , positive predictive value was 82.6% and negative predictive value was 75.8% when Compared against Autoanalyzer. A study done by Yadav K et al[18] among ANC mothers found that device A (sensitivity: 86% and specificity: 83%) had relatively higher sensitivity and specificity compared to Device B (sensitivity: 78.9% and specificity: 81%) when compared against automated analyser which was also relatively higher than the present study.

In a study done by Khanam et al[20] to find validiy of digital hemoglobinometer among antenatal mothers in a facility setting in India found that proportion of anemia using the hemoglobinometer was 64.7% while using the hematologyanalyzer was 52.9%. Device A showed a sensitivity of 97.22%, specificity of 80.30%, and diagnostic accuracy of 86.3%, which are comparatively higher than the present study. Khanam et al[20] study also found that there was a substantial agreement between digital hemoglobinometer and automated analyser indicated by Cohen's kappa coefficient (kappa = 0.72) this in contrast to the present study where there was only a moderate agreement between two devices with Cohens Kappa coefficient estimated to be 0.43.

The findings of this study indicate that the digital hemoglobinometer have moderate agreement with automated analyzers, but false negatives were only 19. Out of that in 11 individuals hemoglobin estimated by digital hemoglobinometer was only less than 0.5g/dl than in the automated analyser and the differences in hemoglobin among the remaining 8 persons were between 0.5 to 1 g/dl. All the 19 false negative individuals were only mildly anemic. Therefore, digital hemoglobinometer did not miss any moderate or severe cases. Digital hemoglobinometer also showed more positives, false positives can be confirmed by the diagnostic test. Hence digital hemoglobinometer can be used as a screening tool.

The limitation of the study was authors tested only one type of digital hemoglobinometer but however, this study forms the base for future higher research involving a large sample size and for testing different types of digital hemoglobinometers.

Conclusion and recommendation:

The Digital Hemoglobinometer exhibits sensitivity of 75.641%, specificity of 76.702% and 76.47% of agreement for diagnosis of anemia with Cohens K of 0.43(Moderate agreement)making it a valuable tool for anemia screening in educational settings. This finding is particularly significant in low-income regions where access to advanced laboratory equipment may be limited. Implementing the Digital Hemoglobinometer for routine hemoglobin assessment in school health programs can contribute to early detection and timely interventions, ultimately improving the health and well-being of school children. Future studies can be planned by lowering the hemoglobin cut-off to diagnose the anemia by digital hemoglobinometer so that sensitivity can be raised and even mild anemia cases may not be missed.

Declaration:

Funding: Nil

Conflict of Interest: Nil

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