ORIGINAL ARTICLE

Bali Medical Journal (*Bali Med J*) 2017, Volume 6, Number 1: 121-124
P-ISSN.2089-1180, E-ISSN.2302-2914

Accuracy in measuring hemoglobin concentration using portable hemoglobinometer method

Zaimah Z Tala,[1*] Dewi Masyithah Darlan,[2] Julius Tantono,[3] Nurfida K Arrasyid[2]

ABSTRACT

Introduction: Anemia is defined as a condition that arises due to as low concentration of hemoglobin in blood. Anemia affects a variety of population groups, cutting across different geographical boundaries and income groups, affecting all, including low-, middle-, and high-income countries.[1] Anemia can cause cognitive disorder, affecting performance in both work and school and reduce the earning capacity of the affected individuals.[2] In Indonesia, based on RISKESDAS data in 2007, it was found that 11.3% women, 12.2% men, and 12.8% children suffered anemia.[3] And the WHO data collected between 1993 and 2005 globally revealed that 47.4% preschool-age children, 41.8% pregnant women, 30.2% non-pregnant women, 25.4% school-age children, 23.9% older adults, and 12.7% men suffer anemia.[4] Anemia is a public health challenge in Indonesia and mostly affects preschool children and women of reproductive age.

Numerous methods have been used and developed to measure hemoglobin concentration in human blood, but not all of the methods are easy and sensitive and effective in diagnosing anemia. The objective of this study is to know the extent of accuracy in measuring hemoglobin concentration using the well-known portable hemoglobinometer method.

Research Design and Methods: This study was a diagnostic test and cross-sectional methods were used. The sampling technique used was total sampling. The total study sample comprised 48 participants. The study was conducted in the Public Elementary School 101747, Klumpang Kebun, Hamparan Perak District, between March and December 2016. Analysis was performed using a 2×2 table, in order to calculate a variety of item measures, including the following: sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, and an ROC graph was made to determine the cut-off point of Hemoglobinometer.

Results: The study results were as follows: sensitivity 0%, specificity 95.8%, positive predictive value 0%, negative predictive value 95.8%, positive likelihood ratio 0, negative likelihood ratio 1, and area under the curve of ROC graph 50%.

Conclusion: The study findings encourage us to conclude that the results arrived at were specific, given the high specificity (95.8%) and high negative predictive value (95.8%). However, the sensitivity of this method as well as its positive predictive value were zero.

Keywords: Portable hemoglobinometer, hemoglobin, anemia

Cite This Article: Tala, Z.Z., Darlan, D.M., Tantono, J., Arrasyid, N.K. 2017. Accuracy in measuring hemoglobin concentration using portable hemoglobinometer method. *Bali Medical Journal* 6(1): 121-124. DOI:10.15562/bmj.v6i1.395

[1]Department of Nutrition, Faculty of Medicine, University of Sumatera Utara
[2]Department of Parasitology, Faculty of Medicine, University of Sumatera Utara,Indonesia.
[3]Medical Student, Faculty of Medicine, University of Sumatera Utara, Indonesia.

*Correspondence to: Zaimah Z Tala, Ms. Sp.GK, Jl. Dr. Mansur No 5 Medan 08126093012
dmasyithah@hotmail.com

Received: 2016-12-20
Accepted: 2017-2-22
Published: 2017-2-25

INTRODUCTION

Anemia is caused by low hemoglobin concentration in blood and is known to affect a wide range of population groups and income categories across the globe, including low-, middle-, and high-income countries.[1] Anemia does not only affect health but also lead to cognitive disorder, low performance in school, reduce earning capacity and thus income, and decrease productivity at the workplace.[2] A study showed that children without anemia demonstrated much better performance than those who suffered anemia.[5] In the case of working adults, anemia can adversely affect work performance and reduce it considerably or altogether render them unable to work.[6,7] Anemia can occur for a variety of reasons, including the following: iron deficiency, infection, cancer, acquired or hereditary disorders, bleeding, and so on.[1] According to the 2001 WHO data on developing countries, 30% of the children aged between 0 and 4 years and 48% of the children aged between 5 and 14 years are anemic.[1]

Anemia continues to remain a moderately severe public health problem in Indonesia, especially children aged < 12 years and in non-pregnant and pregnant women aged > 15 years; the rate of prevalence ranged from 20–39.9%. A study in Medan reported the rate of prevalence of anemia among schoolchildren was 33.3%.[8] Furthermore, the most common cause of anemia is iron deficiency.[4] Anemia is a public health challenge in Indonesia and mostly affects preschool children and women of reproductive age.

According to RISKESDAS data in 2007, 15.6% women, 25.3% men, and 17.1% children suffered anemia in North Sumatera. Whereas in Indonesia, 11.3% women, 12.2% men, and 12.8% children suffered anemia.[3] According to the WHO regional survey data for the period 1993–2005, 76.1% preschool-age children, 69% pregnant women, 73.5% non-pregnant women, 33% school-age

children, 40.2% men, and 39.1% older adults suffered anemia. Globally, it was found that the worst-affected population group suffering anemia was preschool-age children with a prevalence rate of as much as 47.4%.[4]

As shown above, anemia has indeed become major health problem in Indonesia. Our study findings amply support the fact that the method used to ascertain hemoglobin concentration in human blood was easier and more practical and accurate. Nowadays, however, numerous tools and methods have been developed by many manufacturers that help clinicians in measuring blood hemoglobin concentration practically anywhere and anytime. This study, however, focused on just one method—portable hemoglobinometer—which had several advantages to its use: easy to carry, easy to use, and speed with which measurements can be carried out. This tool has been modified so that doctor doesn't need to send blood sample to laboratory. In other words, the doctor can use the portable hemoglobinometer anywhere and anytime to quickly obtain results in a very short time span of just 10–15 seconds.

Portable hemoglobinometer is easy to use and practical, but we need to know the accuracy of this method. Therefore, we decided to compare this test equipment with another equipment called "automated hematology analyzer." Automated hematology analyzer requires more quantities of blood and consumes more time than portable hemoglobinometer.[9] Moreover, this method can be used only in a laboratory.

Diagnostic tests are used by clinicians to identify the presence or absence of disease for developing a suitable treatment strategy. Studies on diagnostic tests' accuracy usually relate the findings derived using a new equipment to an existing reference test equipment, which is used as a benchmark or the best test equipment available to compare and ascertain the efficacy or accuracy of the new test equipment.[10] Since our studies involved the use of the portable hemoglobinometer, we chose to determine its accuracy against to the reference method using vein blood sample. The main goal of our study was to know the accuracy of portable hemoglobinometer in measuring the blood hemoglobin concentration.

RESEARCH DESIGN AND METHODS

A diagnostic test, including a cross-sectional study, was conducted to determine the accuracy of portable hemoglobinometer in Public Elementary School 101747, Klumpang Kebun, Hamparan Perak, Deli Serdang, North Sumatera. Participants recruited for this study were enrolled in 2016. Samples were

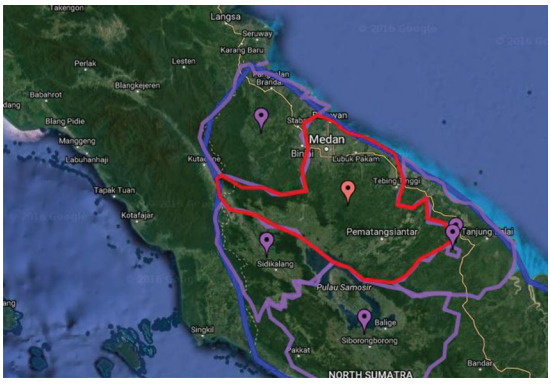

Figure 1 Map of Deli Serdang (red mark), North Sumatera

obtained by total sampling method, which used the following selection criteria to determine the eligibility of participants to participate in our study. The section criteria included the following: (1) students enrolled in Public Elementary School 101747, and (2) students from Grade 3 to 6. The exclusion criteria used for filtering or not recruiting students included the following: (1) Students who did not receive permission from their parents or did not permit the researchers to draw a blood sample, and (2) students who did not come on the day scheduled for the test.

About 4 mL of blood sample was collected and stored in the blood sample tube using EDTA coagulant. Hemoglobin concentration was measured using two methods: automated hematology analyzer SYSMEX T-2000i, and portable hemoglobinometer Family Dr Hb. Data were analyzed using statistics program, and the results were drawn and presented in a 2×2 table, for calculating the sensitivity, specificity, predictive value, likelihood ratio, and the ROC curve yielded by the portable hemoglobinometer.

RESULTS

From the data collected and analyzed, we found that 2 of 48 students (4.16%) were diagnosed with anemia (hemoglobin < 11 mg/dL) by the reference method, and no students were diagnosed with anemia by the portable hemoglobinometer. The mean value of hemoglobin concentration arrived at in the reference method was 13.17, whereas it was found to be 14.17 in the portable hemoglobinometer. We also found that the median value of hemoglobin concentration with the reference method was 13.3 and that the median value of hemoglobin concentration with the portable hemoglobinometer was 14.2. This finding showed that the portable hemoglobinometer gives more accurate results than the reference method. Based on the data presented in Table 4, it can be seen that the sensitivity was 0%,

Published by DiscoverSys | *Bali Med J* 2017; 6 (1): 121-124 | doi: 10.15562/bmj.v6i1.395

specificity 100%, negative predictive value 95.8%, positive likelihood ratio 0, and ROC curve 50%.

DISCUSSION

Hemoglobin measurements are used commonly to identify individuals for anemia, to disseminate among target populations the findings about the critical need for boosting iron in the body, and to assess responses to nutritional interventions. The portable hemoglobinometer (PHM) system has been widely used for its specific features in the recent years because it is portable so does not require a lab setting, requires only a small amount of capillary blood, is relatively cheap and easy to use, does not require refrigeration of the sample or even electricity, and gives results immediately in a digital display.[12]

This study found that the proportion of the presence of anemia among the participants was 4.16%, which was lower than the findings reported in the other study conducted in Amplas, Medan. They reported that the proportion of anemia among schoolchildren was 33.3%.[8] Their results showed that the sensitivity was 0%, which means the ability of their test to diagnose anemia was 0. A specificity of 100% indicates that the probability of the test showing negative results for a healthy subject was 100%. Positive predictive value could not be calculated because neither true-positive nor false-positive values showed up. A negative predictive value at 95.8% indicates that the probability of having a real negative result from all the negative results is 95.8%. Positive likelihood ratio 0 means the ratio between a sick subject getting a positive result and healthy subject getting a positive result. Negative likelihood ratio 1 means the ratio between a sick subject getting a negative result and a healthy subject getting a negative result.

The area under curve of the ROC curve was 50%. This indicates a clear shortcoming; that is, if the method is used for 100 people, only in 50% of the cases the results will be true. The *p* value obtained was > 0.05; this means the AUC (Area Under Curve) 50% shown by the portable hemoglobinometer has no different meaning. Pre-test probability (prevalence) shows the probability of subjects having disease before the test was done, whereas post-test probability shows the probability of subjects having disease after the test was done.[13]

The likelihood ratio can vary from 0 to infinity. The bigger the positive likelihood ratio value, the more convincing the test result obtained showing the real presence of the disease. If the positive likelihood ratio is near 0, the probability of subjects having the disease is lower.[14] The positive likelihood ratio obtained in this study was 0; thus, this the post-test probability value becomes 0.

A study conducted in Honduras reported that for a 6-μL blood sample the sensitivity was 82%, specificity 84%, positive predictive value 83%, and negative predictive value 83%. In central Bangladesh, a study reported that the sensitivity was 91%, specificity 77%, positive predictive value 95%, and negative predictive value 61%. In a study conducted in San Pedro Sula, it was reported that the sensitivity was 75%, specificity 77%, positive predictive value 95%, and negative predictive value 61%.[12]

The hemoglobin concentration values obtained from these two methods were different. This can be due to the difference in reagents used and the photometric wavelength, although the principle is the same. In the reference method, erythrocytes is lysed by surfactant and then the globin group molecule is altered by Sodium Lauryl Sulfate to SLS-Hb. After this step, a spectrophotometer with 540-nm wavelength was used.[14] However, in the portable hemoglobinometer method, erythrocytes are lysed by the surfactant in the strip test to release hemoglobin, then the color intensity is measured by illuminating the application area using LED, and the intensity of the reflected light is measured with a reflectance photometer (525 nm).[15,16] The results obtained in this study were correlated with a low prevalence of anemia among the subjects of the study. The lower the prevalence, the higher the number of sample participants needed.[11]

CONCLUSION

Based on the results obtained in this study, especially the high specificity (95.8%) and high negative predictive value (95.8%), it can be concluded that our study which took place at Public Elementary School 101747, klumpang Kebun, Hamparan Perak, Deli Serdang, North Sumatera, was indeed specific and accurate. However, the sensitivity value and positive predictive value were 0.

We recommend that this method be further developed to fine-tune the test procedures and enhance its efficiency and accuracy. As for the prevention of anemia, although only two students were diagnosed with anemia, precautionary and preventive measures are still required and the schools should formulate and implement strategies to give students health education and pay attention to student's hygiene and sanitation, teach them to develop good attitude, and help them understand the importance of consuming healthy foods and drinks. It is the responsibility of both the school and the students' parents to teach their children

not to litter, flush the toilet after use, wash hands with soap, maintain hygiene, and eat healthy food (cooked).

ACKNOWLEDGMENTS

The authors are grateful to the children of *Public Elementary School 101747, Klumpang Kebun, Hamparan Perak, Deli Serdang, North Sumatera* for their enthusiastic participation in this study. The support provided by the principals, teachers, and parents of these children was also invaluable.

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