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Hemocue Validation for the Diagnosis of Anaemia in Children: A Semi-Systematic Review

Gwetu TP*, Chhagan MK, Craib M and Kauchali S
Department of Public health, University of KwaZulu-Natal, Durban, South Africa

Abstract

Background: Numerous methods are endorsed for Haemoglobin (Hb) estimation and anaemia assessment. The Hemocue is being introduced for routine use in clinics and hospitals in many developing nations. There are a number of illustrative cases that establish a clinical connection readily, but these have mainly been with adults. This study seeks tore view literature on the diagnostic accuracy of the Hemocue among children.

Methodology: This is a semi-systematic review of studies analysing the Hemocue device's diagnostic accuracy determining haemoglobin levels among children aged zero to fifteen years.

Results: 18 studies were included. The main finding of this investigation is that the Hemocue system is a good screening test, being sensitive and reliably projecting necessity of a full blood count. It is not likely that diagnosis of a clinically significant condition can be overlooked by this investigation. Thus it would seem to be a useful method to use for Hb screening in appropriate situations. The studies reviewed generally reported a difference between the means obtained by Hemocue Laboratory analyser, though these did not reach statistical significance. A trend for underestimation of Hb values was reported with most studies. The Hemocue had a sensitivity range of 75-91%, specificity range of 88-100% and positive predictive values ranging from 75-80% for the detection of anaemia. The mean difference in Hb from paired samples ranged from 0.2- 0.35 g/dl (0.7%).

Conclusion: The Hemocue is comparable to usual laboratory methods for determination of Hb level in children. It is well appropriate for use in care of healthy paediatric patients and children with hematologic disorders. A full blood count is recommended when anaemia is identified or in suspected non-anaemic iron deficiency.

Keywords: Anaemia; Diagnosis; Screening; Hemoglobinometry; Accuracy; Precision

Introduction

Haemoglobin (Hb) concentration is the most consistent anaemia indicator [1]. Most reliable methodologies for testing Hb concentration require some equipment that may not be available in primary care sites. The Hemocue measures Hb level in undiluted capillary or venous blood. It is easily transportable, needs very little blood for analysis, does not require blood sample storage or refrigeration, gives immediate digital results and can be battery operated. The device seems appropriate for field surveys, anaemia surveillance at sentry sites and to evaluate the impact of nutritional intervention programs. For example, until three years ago the South African Blood Transfusion Service used only the CuSO4 method for Hb measurement in potential blood donors. Now, all of their sites have changed to the Hemocue system. The Hemocue is also being rolled out to clinics and hospitals of South Africa where it has found widespread acceptance and is being used for rapid Hb assessment of both adults and children. This study reviewed the validity of the Hemocue compared to laboratory reference methods in children.

Methods

Inclusion criteria for studies

Two reviewers identified studies, extracted data, assessed methodological quality and compared results of studies analysing the diagnostic accuracy of the Hemocue with comparisons made against a laboratory based Hb analyser. Samples were population or hospital based. We also included studies that assessed Hemocue test reliability. This study focuses on anaemia detection in children from neonates up to age fifteen years. Electronic databases such as PubMed, Medline and Science Direct were explored using keywords such as Hemocue, Hb tests, anaemia screening, reliability and validity. Dates ranged from the early seventies when the Hemocue was invented up to January 2013. A semi-systematic literature review was applied; using two thematically separated data collection forms. Articles were reviewed in stages and by categorization. Available abstracts in English were all read before deciding which relevant full text to retrieve. We scored studies according to pre-determined criteria such as the evidence for accuracy, precision and potential clinical usefulness (unpublished observations). The decision on which studies to include in this research was made after further considering available data from each study using a specifically formatted inclusion form. The pre-designed inclusion form contained data on study quality, design and characteristics such as location, laboratory reference method used to assess Hb concentration, health care setting, age restrictions, sample size and outcome. A systematic review or meta-analysis would subsequently examine in more detail the limits to and determinants of efficacy in the identified studies and provide an exhaustive summary of literature relevant to the research question

Results

Description of Studies

35 studies were found which analysed Hemocue Hb testing in children. Only 18 studies met the research criteria and were included in this study. These studies used dissimilar Hemocue devices, statistical

***Corresponding author:** T P Gwetu, Department of Public health, Maternal and Child health unit, University of Kwazulu-Natal, P/Bag 7 Congella, Durban, 4013, South Africa, Tel: +2733 387 9562; E-mail: tgwetu@gmail.com

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analysis and sources of blood. The study objectives, patient morbidity status, age range, health care setting in which studies were carried out varied between studies. This makes direct comparison of study results, and generalization to different clinical contexts, challenging. The quality of the research studies was assessed according to three broad criteria – validity, relevance and freedom from various biases such as flawed study design and selection bias. The included studies had a formulated problem which was addressed effectively and revealed understanding of past research. A summary of findings for the included studies is provided in appendix 1.

Accuracy

This review found that the Hemocue was generally precise and had good correlation to reference laboratory tests. The device was accurate within 12% over a wide Hb range. A comparison of the Hemocue against the laboratory Hb analyser found the device to have a sensitivity range of 75–91%, specificity range of 88–100% and positive predictive values ranging from 7580% for the detection of anaemia. The mean difference in Hb from paired samples measured by Hemocue and the laboratory analysis ranged from 0.20.35 g/dl (0.7%) and standard deviation ranged from 0.37-1.1 g/dl (7%). Variances of more than 1.0 g/dl were found in about 6% of measurements [2-10]. The studies reviewed generally reported a difference between the means obtained by Hemocue vs. Laboratory analyser, though these did not reach statistical significance. A trend for underestimation of Hb values was reported with most studies. In one study this tendency was said to increase with increasing Hb. Under-estimation of Hb values can lead to an over-estimation of anaemia. The underestimate of Hemocue values ranged from 5 to 15%, with a variance in mean Hb up to 0.35 g/dl in non-anaemic subjects, 0.33 in anaemic and 0.42 in children with haematological disorders [4,5,6,11,12].Though this was the common finding, a few researchers found either no difference in mean values [13] or overestimation of Hb values [7,14,15]. One study reported both under- and over-estimation of Hb values. Neufeld et al. [8] found that the device underestimated Hb in capillary blood for concentrations under 12.5 g/dl and overestimation at higher values [8].

Test conditions need to be considered carefully. An important error of note reported by some researchers was a positive bias which considerably reduced accuracy. Reporting bias potentially leads to over-representation of studies with significant or positive results in systematic reviews. These biases make positive studies easier to find than those with non-significant results, something that we can tried to minimise by extensive searching. The Hemocue showed a positive bias of approximately0.3 to0.7 g/dl. Bias reporting was very low ranging from an observed bias of 0.4% [7] to 0.9% [2].

Precision

The Hemocue was generally very reproducible. There were generally no significant differences between repeat measures of the same sample of blood or in serial samples from the same patient. A wide variation was, however, reported between repeat Hemocue measurements using single drops of blood from the skin puncture site. Mixing of blood drops before analysis improved precision [2,3,6-8]. The Hemocue revealed good retest reliability. This was comparable to the laboratory reference method with concordance coefficients of 99% and coefficients of variations (CV) of 0.6 to 1% for both techniques [3,4,6-8]. The Hemocue gave values similar to those of the laboratory method for a widespread series of Hb values performed in different circumstances such as with anaemic patients, non-anaemic children and in patients with haematological disorders [11,12,16]. One study described high within-subject inconsistency demonstrating unreliability. The researchers reported differences when capillary blood was obtained from the left hand as well as the right hand and compared (Variance 6.3%). Differences were also noted when Hb values were measured on four consecutive days (Variance 7.0%). Reliability in the two approaches was low, being 69% when measurements were made from different sites and 50% on different days [17].

Venous versus capillary blood samples

Acceptable precision was found in most studies comparing capillary blood samples to venous blood samples. The accuracy of the Hemocue method was very good when venous blood was used with high correlation coefficients of greater than 0.90 and concordance coefficient of about 98%. Generally the Hemocue device presented a slightly lower Hb value when compared to laboratory analysers with a modification of about 0.5g/dl [7,8-10,16]. Hb measurement from capillary blood in children had greater variability than that generally reported for adults. The mean Hb in capillary samples was higher than that from venous samples. Capillary Hb values were on average 0.35-0.5 g/dl (3.5-4.8%) higher than those reported for venous blood - in about 70-85% of paired samples. The largest discrepancies in Hb concentrations between venous and capillary were reported in the neonatal period and specifically in acutely ill children, with the Hemocue producing lower values than the laboratory analysers. The highest difference between the two sample types was seen in anaemic children [8,9, 16,18,19].

One study compared the performance of two types of Hemocue devices. The Hb-201+ device and the B-Hb device showed higher limits of agreement for venous than for capillary blood. Association coefficients between the two devices were significantly high for venous samples (95%).Correlation was less (85%), but still significant for capillary blood. Combined use of different Hemocue devices in a survey could affect results particularly when using capillary blood [9].

Clinical usefulness and field/Hospital Hb testing

Convenience, reliability and suitability for rapid surveys were a common finding reported with regards to use of the Hemocue for Hb measurement. Many technicians ranked the Hemocue as the most user friendly non-laboratory method of assessing Hb. The device was simple to operate and easily portable. Rapid digital display of results was also an advantage. Even in a hospital setting, significant time savings were observed [2-5]. The small blood sample volume used was an advantage especially where repeated blood samples were needed with neonates and growing children [4]. Experience of the operator was not a factor, training was unceremonious. A key benefit was the lack of reagent dilution of the blood samples [2,3]. The Hemocue showed very good reproducibility. Instrument error could therefore be excluded as an important factor for error causing unreliability. Accordingly, figures acquired in the field can be acknowledged as being of equal reliability as that from hospital-based studies [6-8]. As expected, accurate results were mostly attained in controlled circumstances, i.e. hospital based as compared to field setting.

Improved precision of Hemocue Hb measurement was obtained by pooling and mixing drops of blood before examination. Humidity was also reported to affect Hb assessments when the Hemocue device was used in tropical health centres. Humidity changed the analysis outcome resulting in an underestimation of Hb of about 2.0 g/dl [2,3,8]. Overestimation of anaemia may result if relying on Hemocue Hb estimations in tropical clinics that do not have adequate storage and handling protocols in place for the cuvettes. Technician error would then be accountable for most erroneous results obtained.

Advantages were noted over laboratory testing with regards to patient management particularly with regards to cost savings and the timeous result [4]. However, some studies found the micro-cuvettes used for the Hemocue to be costly and sometimes problematic to obtain particularly in under-developed nations. Efficiency was reduced due to difficulties in sustaining a sufficient supply [3,5]. Unfortunately, no apparent solution to this problem exists at this time.

Discussion

When used under standard conditions, the correlation of Hb values from Hemocue and automated laboratory methods was good. Our review of the results suggest that compared to laboratory based methods, which are the standard in Hb measurement, the Hemocue device requires an upward adjustment of about 0.5 g/dl when interpreting results. It is probable that the cause for differing reports on over- and under-estimation of Hb values, as well as the differing concentrations of venous and capillary Hb lies in variations in blood collection technique as well as different Hemocue devices and laboratory analysers. Variances of more than 1.0 g/dl were found in about 6% of measurements. Discrepant values more than 2 g/dl were seldom reported in the studies outlined but are note-worthy as these may lead the clinician to take different clinical action. Children can be over-treated or over-investigated. Most studies in this review focused on Hemocue testing in ambulatory settings, hence utility in acutely ill patients cannot be generalised. For hospitalised patients, individual considerations will determine how the Hemocue and laboratory analysers are used most appropriately. Children receiving intensive care are at risk of lowered blood levels attributed to repeated collection of blood for laboratory tests. Laboratory Hb monitoring can be substituted with Hemocue Hb measurement. Hb testing using the Hemocue cannot substitute the complete blood count in seriously ill patients as platelet and white cell counts have to be considered in the clinical management of most ill hospitalized individuals. The studies reviewed were generally cross-sectional studies. Little was mentioned on the prevalence of anaemia in the sample populations. This makes it difficult to assess the positive and negative predictive values of the test as this depends on prevalence.

The Hb value alone is an important primary screening assessment. This is expected to give a dependable extrapolation on whether a full blood count is necessary. In primary settings or routine surveillance a full blood count rarely contributes significantly to the understanding of a child's health status. A full blood count is required when anaemia is detected, when clinical signs are present or when indicated by a child's history. Evidence in support of or in contradiction of this proposition is needed through studies in diverse environments. Good reliability adds support to its use in monitoring response to treatment.

Limited and careful requests from health practitioners for full blood counts could improve efficiency, convenience and cost. The cost of a full blood count includes blood sample collection, laboratory charges, printed test reports and time. A major benefit of the Hemocue for field studies and general practice is the convenience of it being portable and transportable. The Hemocue avoids time losses as the complete test takes at most five minutes. The client departs from the health centre with current Hb values in hand and clinical decision implemented.

Recommendations

- From the published studies it appears that the Hemocue is both accurate and reproducible for the measurement of Hb. Thus it would seem to be a useful method to use for Hb screening in appropriate situations such as at primary healthcare centres without laboratory facilities and field surveys.
- When measuring Hb on the Hemocue, a downward adjustment of about 0.5 g per dl may be necessary for comparison of capillary to venous blood samples. The bias to relatively higher values by the Hemocue, makes it is likely that venous haemoglobin values could generally be about 0.5 g/dl lower than that of skin puncture samples.
- Further validation of Hemocue use in children is recommended in diverse settings, such as specific age groups (preschool and school age children), tropical climates and field work based studies.
- Research in large non-anaemic sample populations with low anaemia prevalence is essential for determining positive and negative predictive values for the Hemocue test as compared to the laboratory analysers.
- Research is needed in primary care settings comparing usefulness and constraints of the Hemocue as compared to a laboratory based test of measuring Hb. This is essential particularly in resource poor nations and continents such as Africa.

References

1. World Health Organization (2011) Haemoglobin Concentrations for the Diagnosis of Anaemia and Assessment of Severity, Geneva.
2. Mills AF, Meadows N (1989) Screening for anaemia: evaluation of a haemoglobinometer. Arch Dis Child 64: 1468-1471.
3. Johns WL, Lewis SM (1989) Primary health screening by haemoglobinometry in a tropical community. Bull World Health Organ 67: 627-633.
4. Rechner IJ, Twigg A, Davies AF, Imong S (2002) Evaluation of the HemoCue compared with the Coulter STKS for measurement of neonatal haemoglobin. Archives of disease in childhood Fetal and neonatal edition 86: 188-189.
5. Lara MAM, Kandulu J, Chisuwo L, Bates I (2005) Evaluation and Costs of Different Haemoglobin Methods for Use in District Hospitals in Malawi. Journal of Clinical Pathology 58:56–60.
6. Hinds LE, Brown CL, Clark SJ (2007) Point of care estimation of haemoglobin in neonates. Archives of disease in childhood Fetal and neonatal edition 92: 378-380.
7. Spielmann N, Mauch J, Madjdpour C, Schmugge M, Weiss M, et al. (2012) Accuracy and precision of hemoglobin point-of-care testing during major pediatric surgery. Int J Lab Hematol 34: 86-90.
8. Neufeld L, Garcia-Guerra A, Sanchez-Francia D, Newton-Sanchez O, Ramirez-Villalobos, et al. (2002) Hemoglobin measured by Hemocue and a reference method in venous and capillary blood: a validation study. Saludpublica de Mexico 44: 219-227.
9. Monárrez-EspinoJaR, N (2008) Comparison of the Analytic Performance between the BHB and HB-201+ HemoCueHemoglobinometers for Venous and Capillary Blood under Field Work Conditions. Ecology of Food and Nutrition 47: 11.
10. Kruske SG, Ruben AR, Brewster DR (1999) An iron treatment trial in an aboriginal community: improving non-adherence. J Paediatr Child Health 35: 153-158.
11. Edmond K, White A, Paterson B (2001) Community Based Diagnosis and Treatment of Anaemia in NT Aboriginal Children. Darwin: Territory Health Service.
12. Cohen AR, Seidl-Friedman J (1988) HemoCue system for hemoglobin measurement. Evaluation in anemic and nonanemic children. American journal of clinical pathology 90: 302-305
13. Nkrumah B, Nguah SB, Sarpong N, Dekker D, Idriss A, et al. (2011) Hemoglobin estimation by the HemoCue® portable hemoglobin photometer in a resource poor setting. BMC Clin Pathol 11: 5.

14. Bhaskaram P, Balakrishna N\, Radhakrishna, Krishnaswamy KV (2003) Validation of Hemoglobin Estimation Using Hemocue. India: National Institute of Nutrition Indian Council of Medical Research. Indian J Pediatr 70: 25-28.

15. Emond AM, Hawkins N, Pennock C, Golding J (1996) Haemoglobin and ferritin concentrations in infants at 8 months of age. Arch Dis Child 74: 36-39.

16. Hinchliffe RF, Anderson LM (1996) Haemoglobin values in venous and skin puncture blood. Arch Dis Child 75: 170-171.

17. Morris SS, Ruel MT, Cohen RJ, Dewey KG, de la Brière B, et al. (1999) Precision, accuracy, and reliability of hemoglobin assessment with use of capillary blood. Am J Clin Nutr 69: 1243-1248.

18. Kayiran SM, Ozbek N, Turan M, Gurakan B (2003) Significant differences between capillary and venous complete blood counts in the neonatal period. Clin Lab Haematol 25: 9-16.

19. Bellamy GJ, Hinchliffe RF (1988) Venous and skin puncture blood counts compared. Clin Lab Haematol 10: 329-334.