PalArch's Journal of Archaeology of Egypt / Egyptology

REVIEW ON HEMOGLOBIN COLOUR SCALE

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Navya Khanna, M.P.Brundha*. REVIEW ON HEMOGLOBIN COLOUR SCALE-- Palarch's Journal Of Archaeology Of Egypt/Egyptology 17(7), 1357-1365. ISSN 1567-214x

Keywords: Micro Business Unit, Competitive Strategy, Performance

ABSTRACT

The Haemoglobin Color Scale was designed for WHO as an easy , affordable, pocket-sized device to provide real-value haemoglobin reading within 1 g / dL. It is intended for the clinician / health worker without easy access to a laboratory, and thus plays an important role in managing anaemia in peripheral health services, especially in under-resourced areas, as well as in antenatal and child health initiatives, screening blood donors, and point-of-care anaemia tests wherever they may be. When tested against reference hemoglobinometry, an international validation trial and other trials have verified its reliability. When determining the seriousness of anemia, it is much more effective than clinical review. It has been over a decade since the introduction of the Haemoglobin Color Scale (HCS) by WHO which needs only a drop of blood on a special paper compared to a chart of red different shades and is very suitable for resource limited countries. But in detecting anaemia, a systematic review by Critchley and Bates revealed varied HCS sensitivity and specificity. Most studies reported good results and recommended use of HCS, while few reported being too unreliable for general use, especially in places where the haemoglobinometerHemoCue was available.

In this review, we have discussed the background, method of diagnosis and its usefulness along with implementations in major international health programs. By comparing various literature available online, we have evaluated its advantages and disadvantages over other methods of hemoglobin estimation.

INTRODUCTION

A high proportion of the global population are anaemic[1] and it is a major cause of maternal, perinatal and child mortality.[2] The highest cases are seen among children, where it causes low birth weight, delayed mental and physical development along with increased susceptibility to infections.[3] Around 1.62 billion people are affected with anemia, and it contributes greatly to economic loss due to reduced productivity of the working class.[4]In the past decades, in addition to clinical detection of anaemia[5], numerous innovative simple and reliable diagnostic tests and methods for estimating haemoglobin have been introduced in recent decades to help detect anaemia[6–9] in most developed, underdeveloped and developing countries.Throughout developed nations, despite the high incidence of anaemia, screening for childhood anaemia is mostly limited to surgical examination of multiple locations such as nail pad, conjunctiva, palm of the neck, and varied-outcome buccal mucosa.[10]The WHO Haemoglobin Color Scale (HCS) was created and manufactured and distributed under license agreement in response to the need for a "fast , inexpensive and durable tool for measuring haemoglobin by health workers outside the laboratory" [9] the WHO HaemoglobinColour Scale (HCS) was developed and has been produced and distributed under licence agreement by Copack (Oststeinbek, Germany) since 2001.[11,12]The scale comprises a small card of six shades of red (lighter to darker), each representing a haemoglobin concentration of 40 g/L, 60 g/L, 80 g/L, 100 g/L, 120 g/L, and 140 g/L, respectively. A reduction in blood consumed on a generic chromatography filter paper is compared to the color scale, enabling the patient to determine the concentration of haemoglobin in 10 g / L stages, providing an estimation of intermediate outcomes.

HISTORY/BACKGROUND

In most developed countries, pregnancy anaemia leads greatly to maternal mortality and morbidity.[13,14] A haemoglobin concentration (Hb) of < 11.0 g/dl is commonly taken as indicative of anaemia in pregnancy.[15] It is also necessary to raising the anaemia burden in order to meet the Millennium Development Goals of the United Nations dealing with reducing maternal and infant mortality. However, people with the largest anaemia burden are perhaps those that are hardest to meet – the vulnerable and oppressed, women and children and others that do not have access to the health care system.[16]

Effective control of pregnancy anaemia relies on reliable and appropriate methods to diagnose anaemia, determine the severity and track treatment response.[17] Timely diagnosis of women with mild to moderate anaemia is likely to avoid the occurrence of more serious anaemia and therefore minimize the need for blood transfusion and its related complications. Prevention of extreme anaemia also has more concrete advantages for mother and child alike. An agreed quality of practice in developing countries where the incidence of anaemia is below 20 percent is that all women have at least one indicator of [Hb] during pregnancy. This is usually performed by electronic counters. In developing countries with reported prevalence of 40– 70% these methods are often not available, even at the tertiary level. Screening for anaemia may not be performed at all, or may be limited to checking the conjunctiva for pallor involvement. There are no published records of anaemia screening accuracy using conjunctiva-only clinical examination in pregnant women in rural antenatal clinic areas. Studies in children[5] and healthy ambulatory adults[18]have demonstrated poor accuracy. Except when used in conjunction with a conjunctival or anaemia coin, sensitivity remains poor even when there is serious anaemia[8,19]. Thus, there was a need for a simple, cheap but accurate method for the estimation of haemoglobin concentration. The Hemoglobin Colour Scale was developed by WHO for this purpose.

METHOD

The HaemoglobinColour Scale consists of six standard colours varying from pale to dark red, mounted on a rigid card, the colours corresponding to haemoglobin levels of 4, 6, 8, 10, 12 and 14 g/dl, respectively. Such values can be recorded by readers and intermediate values calculated (e.g. 11 g / dl). A blood drop absorbed on a Whatman 31 ETChr paper check strip is compared to the scale standards by shifting it up and down in the middle of each color pattern behind the circular 8 mm holes to calculate the corresponding Hb value. [20]Stott and Lewis explored numerous causes responsible for the large margin of error with the available color scales.1 This prompted them, in conjunction with Wynn 2, to classify Whatman 31ET chromatographic paper as suitable for the preparation of 45 to 15 mm test strips for absorbing blood drops. They established a set of standards consisting of blood samples, the concentration of which was measured by spectrometry using the reference method ICSH3 (International Committee for Standardization in Haematology; Expert Panel on Hemoglobinometry), and adjusted in 2 g / dl steps to obtain a range of 4–14 g / dl.[21]

A computerized analytical spectrophotometer defined the spectral characteristics of the color produced by a drop of blood on a test strip from each of the haemoglobin levels. Such criteria were replicated from pigments of the three primary colors and a neutral diluent in light-resistant printing inks. The pigment shades were then printed on paper sheets at a given density of ink, which was chemically neutral, unbleached, chlorine-free and resistant to UV light to avoid altering the pigment of the dye. The paper was dried and varnished after spreading the ink. The colour strips were mounted on a neutral grey surround with a PVC backing, which would allow any traces of blood to be wiped easily off the back of the scale. The viewing area was reduced to an 8–9 mm diameter circular aperture in the middle of each regular hue. Optimum conditions for color matching were established: the best results were obtained with the scale kept at an angle of about 45 ° with the light (daylight or artificial tungsten or fluorescent light) flowing over the observer 's head. Although the scale is a therapeutic instrument not meant to be compared with the laboratory-based calculation, the latter was used to include comparison measurements to verify the scale 's reliability. Thus, a laboratory-based study of 1213 blood samples showed that anaemia could be detected reliably with training with the scale, and to classify the degree of anaemia correctly in clinical terms as moderate (8 to < 12 g/dl), pronounced (6 to < 8 g/dl), or severe (< 6 g/ dl).

DIAGNOSTIC USEFULNESS OF THE SCALE

In a study by C F Ingram and S M Lewis the diagnostic usefulness of the scale was assessed by comparing readings with the reference haemoglobinmeasurements in four clinically differentiated groups, namely: no anaemia (> 12 g/dl), moderate anaemia (8 to <12 g/dl), pronounced anaemia (6 to < 8 g/ dl), and severe anaemia (< 6 g/dl), the repeat readings being used if there had previously been discrepancies.[22] Diagnostic sensitivity and positive predictive value are measures of the frequency in which a good outcome is accurate, whereas diagnostic accuracy and negative predictive value represent the frequency with which a bad outcome is false. In determining whether anaemia was present and in calculating the degree of anaemia in the therapeutic cut off stages, there was a high degree of precision. The likelihood ratio was calculated by Youden’s method, where values from +0.1 to +1.0 indicate an increasing probability that the test gives correct diagnostic information; the results show that the ratio was high at all values, especially in anaemia with haemoglobin< 6 g/dl.

COMPARISON OF THE SCALE WITH CLINICAL DIAGNOSIS OF ANEMIA

No judgmental errors were made on physical examination in extreme anaemia (haemoglobin, < 6 g / dl) but with higher haemoglobins the physical characteristics became increasingly difficult to detect and interpret. Even when haemoglobin was fine, pallor was diagnosed in 16.6 percent of cases, whereas only 3.4 percent of normal cases were diagnosed with moderate, clinically insignificant anaemia with 10 or 11 g / dl of haemoglobin. At the other hand, while the comparison tests indicated mild anaemia (haemoglobin, 8–9 g / dl), physical testing was not found in one third of patients, while severe anaemia was accurately reported in 97% of cases.

POPULATIONS TO BE INCLUDED

The HbCS plays a potential role in both preventive and curative health care services. The key potential users of HbCS that should be discussed in any research program are the lood transfusion service which helps to detect and exclude anaemic donors. Various malaria and nutrition programmes help to measure success of interventions (though it is more likely that HemoCue® or equivalent would be used in these circumstances). Certain ante-natal clinics for regular anaemia screening and identification of those requiring specific care. Under some clinics for diagnosis of mild, moderate and serious anaemia to guide management strategies. It also provides ARV services, which is screening for pre-treatment anaemia as a guide to effective therapy and monolithic treatment.

CONFLICT OF INTEREST

Researchers with positive or negative interest in producing or selling the HbCS should explicitly state their intentions and any possible effect that could have on the understanding of the findings.

USE OF HEMOGLOBIN ESTIMATIONS BY MAJOR INTERNATIONAL HEALTH PROGRAMMES

SOME FACTORS INTERFERE with anaemia in poorer countries, including malnutrition, poor nutrition, helminth infections, and haemoglobinopathies. Specific approaches based on evidence are available to mitigate or reduce many of those factors. These treatments include the use of bednets and anti-malaria treatment, iron supplements, and' de-worming' services treated with insecticide.

Although almost all major health programs need to address the problem of anaemia, including malaria, ante-natal care, child health, nutrition, and HIV / AIDS, they have different strategies to combat anaemia. It became clear at a consultation meeting of appropriate WHO programmesthat only the program' Making pregnancy healthier' promotes community-based screening on a national scale because this system has a strategy of regularly screening all pregnant women for anaemia. Nutrition services use haemoglobin (predominantly calculated in different surveys by HemoCue ®) as a surrogate indicator of iron deficiency, and compile a haemoglobin level database. Roll Back Malaria also uses tests of HemoCue ® haemoglobin to monitor the efficacy of prevention programmes. Therefore, apart from pre-natal care programs, nearly all other major programs require estimates of haemoglobin that are more accurate than the HbCS can achieve. One potential exception is the HIV / AIDS programme, which is still implementing its anaemia strategy which could need anaemia screening before zidovudine anti-retroviral therapy beginsand as a tool to monitor adverse events. Estimates of haemoglobin are an important component of the blood transfusion process, where they are used both to screen donors and to determine the degree of anaemia in transfusion recipients. Although 12.5g/dl is the recommended cut-off level for blood donors, many countries actually use a level of 12g/dl. The HbCS is not sufficiently reliable to use with a 12.5g / dl cut-off but may be helpful in detecting prospective donors with haemoglobins above or below 12g / dL. The HbCS is considered too imprecise to direct blood transfusion administration.

RECOMMENDATIONS BY WHO

One of the consultation meeting's recommendations was that WHO should specifically de-fine the role of HbCS in public health in ensuring its healthy, relevant, and cost-effective use. To achieve this goal, the WHO needs to provide a mechanism to direct the reach and quality of information required in the areas of operational research, as well as an evaluation of existing use of HbCS. It must also develop a strategy to disseminate information, educational tools and communication strategies on best practice relevant to HbCS use. The focus audiences for this distribution approach would be public health actors, particularly national and foreign policy makers and advisors, as well as researchers involved in pursuing studies on the diagnosis and management aspects of anaemia in public health.

COMPARISON OF LITERATURE

The results verified in a report by MadukaDonatusUghasoro, Anazoeze Jude Madu, that the color scale of the Haemoglobin showed good agreement with that obtained with the HemoCue test.[23] Is similar to what was documented in previous studies the Haemoglobin Color Scale was found to be effective in the diagnosis of serious and moderately extreme anaemia in high prevalence areas in the hands of real-life community health workers under short training.[24] In addition, the sensitivity and specificity of the HCS was remarkable for a screening tool in recognizing anaemic children. Although WHO Hb values of 11g / dl should be used as a cut-off for anaemia rather than the HCS classification of 10g / dl, it is interesting to note that studies have shown that there is an improvement in HCS output as the level of haemoglobin descends to the range of extreme anaemia cut offs. Since the specificity of HCS in this lowhaemoglobin cut-off remains relatively high, combined with the excessive risk of morbidity and mortality associated with severe anaemia, use of HCS may be recommended for the diagnosis and treatment of extreme childhood anaemia in resource poor countries lacking the sophisticated modern equipment of detecting anemia in primary care settings. Despite this poor performance of anaemia clinical evaluation, it remains the only possible performance tool for prompt anaemia assessment at primary health care facilities in developing countries. Our experience and that of Luby et alshowed that parents / caregivers and other non-physicians with minimal training success can learn about the clinical assessment of anaemia by providing different color charts describing three broad categories: not anaemic, anaemic, and extremely anaemic. The subjectivity associated with contrasting parents ' palms which are themselves anaemic will be that.

A study conducted by LeeniyagalaGamaralageThamalDarshana and DeepthiInokaUluwaduge concluded that the color scale of the WHO is a simple, portable and easy method for screening anemia. Although its precision remains high in laboratory-based tests, the accuracy becomes uncertain when it comes to field studies. It was created as an alternative to the clinical evaluation of anemia and not a spectrophotometer, but whenever a spectrophotometer is available, the method should be compared to the WHO color scale system in hemoglobin level measurements. For places where spectrophotometers can not be clinically tested, it could be better than the color scale of the WHO. In future studies large sample numbers are recommended to obtain better results.

ADVANTAGES

HCS is a useful tool for anaemia to be correctly detected and its severity evaluated. It does not compete with laboratory-based haemoglobinometry, since it is intended only as a clinical resource where it is less necessary to obtain an accurate measurement of haemoglobin than to determine what clinical action is needed. It is easy to use and only requires a very brief training session. It is pocket-sized, independent of energy, and can be used in daylight or artificial light of any kind. The test is fast and takes less than a minute. This needs one drop of blood, which can be collected either by puncture of the skin, or by venesection while extracting blood for other studies. It is inexpensive and costs less than two cents per check (US$ 0.02). Therefore, it plays an important role in providing peripheral health services in under-resourced areas with access to health techno-logy. The effectiveness has been shown in general health clinics as well as in antenatal and child health services, in determining when to refer patients with severe anaemia for treatment in hospitals and in screening for anaemia from blood donors. It will also be an extremely useful tool in anywhere for point-of-care anaemia tests.

DISCREPANCIES

There were some differences between the results of the colour scale and a normal laboratory procedure, mainly due to irregularities in applying blood drop to the test strips, but also due to incorrect handling of the scale. With a short training time and by strict adherence to the instructions provided with the tool, errors can be reduced significantly. Results can then be obtained with a sensitivity and specificity level which is clinically efficient.

LIMITATIONS

The haemoglobin level of individuals varies over a very wide range which makes estimation of the average, and therefore the application of the Bland-Altman model, which is based on the average or difference between a norm (HemoCue) and a reference value (HCS), not feasible. A future planned research to ensure a fairly similar number of children with different anaemia rates would be needed to assess the efficacy of HCS at differing anaemia levels. The HCS method itself is straightforward and can be easily done even by comparatively novice laboratory personnel, but it is the most subjective of all methods and it is also difficult to compare the intermediate values (e.g. 12.5 g / dl) to HCS. This approach may be useful for determining the prevalence of anemia in general population in peripheral areas but definitely not appropriate for screening Hb in prospective blood donors.[25]

In conclusion, the HCS is a reliable option for haemoglobin assay if access to HemoCue assay is limited. However, every case of childhood anaemia should be properly investigated doing a minimum of blood examination, to detect the underlying cause and treat, not just correct, the anaemia.

FURTHER STUDIES

Following the laboratory-based validation, preliminary feasibility studies have been conducted which showed that the system is likely to be of particular value for primary health centres in "countries in need," obstetric management, paediatric clinics, malaria and hookworm control programs, blood transfusion donor collection, industrial health checks, and anaemia epidemiological surveys. For a multicentre study in a variety of these areas, a batch of the scales and test strips was made with independent investigators. In chosen multicentre studies the present limited supply is used. On completion of these studies WHO will seek funding to make the colour scale and test strips available for global distribution through the appropriate channels within the organisation at a cost that will ensure that the price is kept to a minimum.

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