UPDATE

Diagnostic efficacy of digital hemoglobinometer (TrueHb), HemoCue and non invasive devices for screening patients for anemia in the field settings- a proposal

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Abstract

It is important to diagnose anemia at an early stage for appropriate and timely management. There is a need to have a device with good diagnostic accuracy, that is reliable and less expensive. Several methods are available for estimation of Hb. These have been reported to be piloted in small settings with encouraging results. However, for the purpose of screening at the national and state levels, we need a method that has high validity and is cost effective. Our study proposes to establish the diagnostic accuracy of some such devices that are available in India against automated analyzers (gold standard) for screening of anemia in laboratory and community settings.

Introduction

Background: Anemia is a public health problem and prevalent throughout the developing world. Out of these nearly half the total numbers of women are from South East Asia (1, 2). In South East Asia, 65.5% of pre-school children, 48.2% of pregnant women and 45.7% of non-pregnant women are found to be suffering from anemia (3).

It becomes important to diagnose anemia at an early stage to prevent future complications as it is one of the most important causes of morbidity and mortality. Assessment of Hb is the first step in investigating anemia. When laboratories are not available, anemia is diagnosed based on clinical signs. This entails a lot of inter and intra observer variations. In rural communities where detection and treatment of anemia is most beneficial, an alternative method, less expensive and reliable is needed.

The measurement of Hb has traditionally relied on the services of a well-equipped clinical laboratory. Direct cyanmethemoglobin method has been the gold standard for hemoglobin estimation and is cheap but time consuming (4). A number of other methods are available such as hemoglobin color scale, Sahli's technique, Lovibond-Drabkin technique, Tallqvist technique, copper-sulfate method, HemoCue and automated hematology analyzers (5,6,7,8). Each method has a different working principle and its own advantages and disadvantages. Simple techniques to measure Hb exist but they are relatively expensive and require commercial reagents and good technical skills to interpret (9).

Hemoglobin is routinely measured using **automated hematology analyzers** in tertiary care settings which are reliable and accurate but expensive. This system is an automated blood cell counter which measures hemoglobin using non-cyanide method.

Three different devices for detection of anemia have been evaluated in India recently (10). The devices included **Hemoglobin Colour Scale (HCS),** Digital hemoglobinometer **(TrueHb version 1) and ToucHb Version Alpha 1.1,** a non-invasive device. The sensitivity of HCS-HLL test was found to be high (92%) with capillary sample but its specificity was 21.9%. Venous blood sample showed a lower sensitivity (69%) but a higher specificity (59.5%). The TrueHb device with capillary sample had a sensitivity of 82.1% (lower than HCS) but a much higher specificity (77.9%). Venous sample fared better in terms of specificity (86.9 v/s 77.9%). Touch Hb device had given a sensitivity of 73.1% and specificity of 51.5%.

A device for use in communities or primary healthcare facilities in resource-poor settings should be inexpensive, rapid, and easy to perform the test with reasonably accuracy. Operational issues while using a device also aid in taking a decision on the feasibility of its use in field settings. We therefore, explored different aspects like ease of use, portability, cost of device, recurring cost, efficiency in daylight, average time taken to perform each test, expertise required and scope of improvements. The findings of this study suggested that diagnostic accuracy parameters of True Hb were better as compared with other devices. However, there were certain operational challenges noted with the use of each device.

Meanwhile, few more devices have been developed by different institutions that have shown encouraging results. However, for inclusion in the national programs, the chosen device has to be cost effective apart from being accurate. Hence the next phase of the study is being proposed that will evaluate all these devices using a standardized methodology

Aims & Objectives

The objectives are the following:

Primary objective: To establish the diagnostic accuracy of Digital Hemoglobinameter TrueHb (newer version), HemoCue and non invasive devices against automated analyzers (gold standard) for screening of anemia in laboratory and community settings.

Secondary objective:

- To establish the level of agreement in the classification of anemia as reported by ANM (using the device that will be found better) and laboratory technician
- To do a cost effectiveness analysis of the devices and selection of the device for use in national programs

Material & Methods

The study will follow a cross sectional design aimed at establishing the diagnostic accuracy. This will be conducted in field settings of two sites in India. These sites would be Medical Colleges with a facility for performing the gold standard test and having a field practice area. From the operational feasibility point, urban field practice area will be selected.

The study population for this study will include adult patients attending OPDs in field practice areas of the medical colleges. Adult patients (age 18-60 years) willing to participate and being routinely investigated will be considered. Seriously ill patients, neonates and children, pregnant women and patients with known bleeding diatheses will be excluded.

Hemaotological Autoanalyzer will be the Gold standard in the study. The index tests will be digital hemoglobinometer (revised version of True Hb, HemoCue) and noninvasive devices (revised version of **ToucHb Version Alpha 1.1, Noninvasive spectroscopic device, Masimo non - invasive pulse oximetry)**

Consecutive eligible patients who are advised Hb estimation routinely in OPDs in urban field practice areas will be subjected to 2 tests: one invasive and one noninvasive test other than the gold standard. A pre-decided schedule will be followed to choose the combination of devices.

Sample for diagnosis accuracy study was calculated using nMaster 2.0 software considering a prevalence of anemia 50%, sensitivity = 82% (TrueHb)(5) and 82% (HemoCue) (11) significance 5%. The sample size of 600 is considered adequate for the study to assess the diagnostic accuracy of each device.

The level of agreement between the ANM and the gold standard in the diagnosis of anemia will be ascertained. Standard methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals) as listed in the literature will be used.

To analyze the performance of the device of high diagnostic accuracy across different temperature ranges, the device found to be the best in the first phase will be tested in extreme weather conditions. The purpose would be to assess the level of agreement between ANMs and technicians for classification of anemia expressed in terms of kappa statistics. Considering the population agreement to be 0.7, sample agreement 0.8, prevalence of anemia 30%, sample size comes to 625. Considering some drop outs or spoilage of samples during transportation, we added 20% extra and that makes the sample size 700.

Operational feasibility of using device in field settings will be assessed. The parameters would include in terms of ease of use, time taken for reading, power back up or battery, breakdown of the device in field situation, number of readings can be taken in one go, shelf life of device, one time and recurring cost, AMC/ warranty period of device, need and frequency of calibration of device.

Results

Economic Evaluation

An economic evaluation would be conducted to assess the relative efficiency of the diagnostic mechanisms. Standard protocols for conducting such evaluation of diagnostic tests would be used (12) A cost-effectiveness analysis will be reported using correct diagnosis as the outcome measure. Correct diagnosis would be defined as agreement of the result of the particular diagnostic method with the gold standard resulting in the calculation of sensitivity and specificity of each diagnostic tool. Analysis will be conducted at 2 levels using intermediate and final outcomes.

Results of cost-effectiveness analysis would be presented as incremental cost per correct diagnosis of one method compared to the other. The intermediate outcome of correct diagnosis will be modelled to final outcomes based on data from relevant literature. A cost-utility analysis will also be conducted reporting incremental cost per QALY gained of one diagnostic test over the other. For this purpose, Health Related Quality of Life will be ascertained from patients at testing points using a standardized EQ-5D tool. QALY values will be ascertained from EQ-5D scores using MTAB standard tariff values and relevant literature. This would render higher comparability and external validity to the study results.

Analysis would be conducted and presented separately from a Government perspective and a limited social perspective.

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