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Evaluation of HemoQR (Haemoglobin Detection test with Mobile based Software) in Hospital Camp Setup using 280 Patient Samples in Comparison to Gold Standard Methods

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Abstract

Anaemia is an error in the biological system which can lead to mortality if the condition deteriorates. India is one of the world's leading contributors of anaemia. The major reason for this disease is malnutrition and women of reproductive age (WRA) and children are one of the most vulnerable groups to this condition and maternal anaemia is associated with increased mortality. Here in this work, we have compared two devices Device A (HemoQR) and Device B [Haematology Analyzer-Fully Automated-5 parts (Erba H560)] in hospital camp setup using 280 samples from patients of different age groups using fingertip pricked blood for the test. The sensitivity, specificity and accuracy obtained from our study was 92.06 %, 98.67 % and 95.75 % respectively. The results of this study were satisfactory when compared to the criteria of Anemia Mukt Bharat" (AMB) program initiated by the government of India's Ministry of Health & Family Welfare which states a sensitivity and specificity of 80% minimum for an invasive digital hemoglobinometer. The results of this study concludes that HemoQR can be an efficient, economical and smart point of care (POC) haemoglobin (Hb) detection test system using a mobile based application for analysing and collecting the data.

Introduction

According to the World Health Organization (WHO), measuring hemoglobin (Hb) levels accurately and on time is critical in identifying and treating anaemia, a disorder that affects roughly one-quarter of the global population. Anaemia, which is defined by a lack of red blood cells (RBCs) or a low Hb content inside them, reduces the blood's ability to deliver oxygen(O_2). This illness is notably frequent in low and middle-income nations, where dietary inadequacies, infectious infections, and poor access to healthcare all contribute to high rates of anaemia, particularly among women and children (Neogi, 2024). In India, anaemia is a serious public health problem, where 58% of the children aged 6–59 months are anaemic. Globally around 47.4% of children and in India, 58% of children aged 6–59 months are anaemic. Diagnosis of anaemia in children using accurate technologies and providing adequate treatment is essential to reduce the burden of anaemia (Ramaswamy et al. 2020). Traditionally, the diagnosis of anaemia has been dependent on laboratory-based methods, which, while accurate, require well-equipped facilities and skilled technicians. This poses a significant challenge in resource-limited settings, where access to such facilities is often scarce (Biswas, 2021). As a result, the development and deployment of portable, easy-to-use, and accurate point-of-care (POC) testing devices for Hb measurement have become a public

health priority (Pathak, 2019). Digital hemoglobinometers are at the forefront of this development. These devices are intended to give quick, dependable Hb measurements in a variety of contexts, from rural health clinics to emergency rooms. They have various advantages over traditional techniques, including the need for venipuncture (in some models), minimum training requirements, and the capacity to produce rapid findings, which is crucial for quick decision-making in clinical practice (Dabas, 2020). The importance of these devices cannot be overstated, particularly in the context of screening programs and routine health checks in remote areas where laboratory infrastructure is inadequate (Patel, 2018). In recent years, several digital hemoglobinometers, such as HemoCue, TrueHb, and others, have been introduced to the market, each claiming to offer accurate and reliable results comparable to those obtained from automated hematology analyzers, which is considered as the gold standard in Hb estimation (Chandrasekaran, 2021). Hemoglobinometers are widely used for the detection of this biomarker as it's a non-invasive method but it does come with flaws in the accuracy, sensitivity and specificity.

This paper seeks to rigorously evaluate the diagnostic accuracy, usability, and overall reliability of these digital hemoglobinometer in comparison to traditional laboratory-based method. The device under investigation is HemoQR. HemoQR is a Hb detection kit which is composed of a detection strip and a smart phone based mobile application which will help in the immediate analysis of the report and the data will be collected in the application itself. It is a POC device user friendly low maintenance system which can be used in different setup. We have already performed the efficiency of this system in different setup and this will be the third study for the HemoQR device as an alternative to digital haemoglobinometers(invasive/non-invasive). The performance of these device will be assessed across various parameters, including sensitivity, specificity and accuracy, with a particular focus on their applicability in diverse environmental conditions, which is often a critical factor in their deployment in rural and underserved regions (Sambit Ghosh., 2024). Furthermore, this study will explore the ease of use of these devices by healthcare providers with varying levels of training, ranging from highly trained laboratory technicians to minimally trained community health workers. The ability of these devices to deliver consistent and accurate results regardless of the user's expertise is vital for their success in field settings (Ghosh, 2020). The study will also address the reproducibility of results when the same patient is tested multiple times under different conditions, providing insights into the reliability of these devices in routine clinical practice (Kumar, 2019). Given the high burden of anaemia and the need for effective management strategies, the findings of this study are expected to have significant implications for public health, particularly in regions with limited healthcare infrastructure. By providing a comprehensive evaluation of digital hemoglobinometers, this research aims to inform policymakers, healthcare providers, and other stakeholders about the most suitable technologies for anaemia screening and management in various settings (Gupta, 2021). This study focusses on further confirming the usability and repeatability of the HemoQR device along with the sensitivity, specificity and accuracy against gold standard Hematology analyzers.

Material and Method

A comparative study was conducted at a hospital camp setup at BC Roy Technology Hospital, IIT Kharagpur, India. The study was performed using total of 280 patients' samples. These samples were run simultaneously on the Haematology Analyzer-Fully Automated-5 parts [Erba H560) and HemoQR.

Test Method

Two test methods using two different devices was performed. Device A was the HemoQR device and the Device B was Haematology Analyzer-Fully Automated-5 parts (Erba H560). The HemoQR is a portable Hb detection kit used to measure Hb as the standard procedure, it has been shown that HemoQR can provide accurate Hb concentration from our inhouse analysis. The technology of determining the Hb level by HemoQR initiates by capturing the image of the test strip. This image will be taken using the camera of the smartphone (IOS /Android based). The camera will be integrated with the analysis properties of our SmartQR technology with a post processing algorithm in our application. SmartQR application will plays a crucial role in ensuring that the captured image is stabilized across various devices. This stabilization is achieved through a sophisticated algorithm that compensates for any inconsistencies in lighting, angle, and other environmental factors, ensuring that the image quality remains high and consistent. On the other hand,

Haematology Analyzer-Fully Automated-5 parts (Erba H560) is an automated blood cell counter intended for in vitro diagnostic use in clinical laboratories. It measures the Hb concentration using a non-cyanide Hb method. The instrument has been proven to provide accurate and reliable results including Hb concentrations. The test is performed by collecting 2 ml of blood in an EDTA vial using disposable syringe under all aseptic precautions. Simultaneously, 0.8cc(10 microliter) capillary blood was collected and applied on the test strip and an image was uploaded of the blood-stained strip on the mobile application, to get the Hb value. The test is performed as stated in the manufacturer's manual using the reagents/kits provided with the instrument as recommended by manufacturers. In separate data collecting forms, the technician and supervisor each recorded the outcomes. An impartial observer made sure that the supervisor and technician did not discuss their findings with one another. All pointed objects were gathered and discarded in accordance with approved practices.

Result

After simultaneously running the 280 samples on Device A (HemoQR), Device B [Haematology Analyzer-Fully Automated-5 parts (Erba H560]. In the table-1, the data from Device B has been considered as gold standard and we have considered the true positive (TP) as patients having Hb levels less than 11 g/dL which was around 58 and patients with Hb levels more than 11 g/dL to be true negative (TN) and that was calculated to be 222. On the basis of that for Device A we have separately calculated the false positive (FP) and false negative (FN). Table-2 shows the FP and FN values of Device A. This helped us to further calculate the sensitivity, specificity and accuracy of Device A. The sensitivity, specificity and accuracy of Device A (HemoQR) was calculated to be 92.06 %, 98.67 % and 95.75 % respectively. These results were satisfactory as the "Anemia Mukt Bharat" (AMB) program by the Government of India's Ministry of Health & Family Welfare has set a standard of 80% in terms of sensitivity and specificity for invasive digital hemoglobinometer. To give a further graphical representation we have showed in Fig.1 the frequency of the difference between the two devices. We have taken number of the test on the 'Y' axis and the difference between the Device A and B is taken on 'X' axis. From the graph we could predict that more than 25 tests showed a difference of less than -0.5 to 0. In Fig.2 the scattered plot graph showed a similar result where the readings of Device A were plotted on to 'Y' axis and the Device B reading was plotted on 'X' axis. The results showed that the Device A and B showed similar readings with minor differences in the reading for some samples.

Device B [Hematology Analyzer]	***True Positive (TP)***	***True Negative (TN)***
	58	222
	Total Number of Patients - 280	

Table 1: Data of TP and TN from Device B.

Device	***Device A (HemoQR)***
False Positive	3
False Negative	5

Table 2

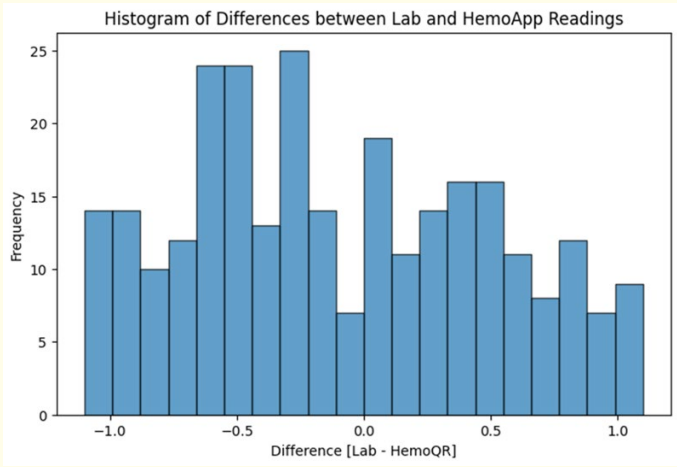

Figure 1: Bar graph of the frequency of the tests performed from Device A and Device B.

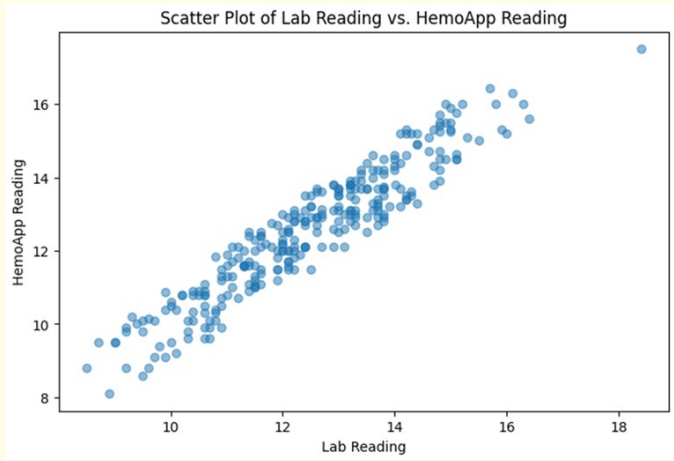

Figure 2: Scattered plot reading of Device A and Device B.

Discussion

The analysis of Hb levels which is the most important biomarker for the determination of anaemia is the key factor for controlling this disorder. The introduction of haemoglobin color scale (HCS) by WHO and hemoglobinometer does give solution to the problem of easing out detection of anaemia to a certain level but they do come with certain limitation in terms of accuracy and, sensitivity and specificity. POCT devices is a potential option for estimation of Hb in peripheral and field settings were the hematology analyzer and laboratory services are not available. So, POCT using digital hemoglobinometers has been recommended as one of the key interventions by the AMB program since 2018 in India. Biswas et al. (2021) reported a simple and an affordable, rapid, and quantitative paper-based sensor integrated with smartphone application for on-spot detection of Hb concentration using approximately 10 µL of finger-pricked blood. The quantitative analytical colorimetry was achieved via an Android-based application (Sens-Hb), integrating key operational steps of image acquisition, real-time analysis, and result dissemination. Their study revealed a successful deployment

of the extreme POC test in rural settings where no infrastructural facilities for diagnostics were available. The experimental study was performed following some steps including the detection steps of the smartphone application. The measured intensities were depicted corresponding to the clinical Hgb levels measured via hematology analyzer. The error bars depicted the standard deviation in the mean intensity obtained from 5 trials corresponding to a particular sample. The results in terms of accuracy, specificity and sensitivity of the device were great but because of the mixing of the two solvent for the test makes this assay a less user friendly. Yadav et al. (2020) and his co-researchers conducted an experimental study which aimed to determine the diagnostic validity of digital hemoglobinometers (TrueHb and HemoCue 301) for screening of anaemia compared to hematology analyzer. TrueHb Hemometer is a battery based operated system which works based on the principle of optical reflectance photometry. HemoCue Hb 301 System is also a battery based operated system which estimates Hb by measuring the absorbance of whole blood at the Hb/HbO_2 isosbestic points at the wavelength of 506 nm and 880 nm for compensation of turbidity.

HemoQR device showed excellent usability, repeatability in hospital camp setup. The sensitivity, specificity and accuracy in this study was calculated to be 92.06 %, 98.67 % and 95.75 % respectively from a pool of 280 samples. These results were similar or in range with the previous study of HemoQR which was done in sub-district hospital. The results of the previous study were 99.08 %, 98.92 % and 99.08% for sensitivity, specificity and accuracy which were done using 200 samples. The minor difference in terms of sensitivity, specificity and accuracy can be because of the handling and operating of the devices. But still, we can conclude from the data that HemoQR is an efficient and a great alternative and it can screen and detect anaemia accurately on field/community basis from venous blood and also from prick at the fingertip which help in the screening of anaemic person.

Conclusion

Accurate, specific and rapid diagnosis of anaemia is very important for making an anaemia mukt Bharat (anaemia free India). Anaemia has become a major public health concern and a challenge even today in India. Anemia is a severe public health problem in India, with more than 40% of the population being anemic. To combat the high burden of anemia in the country, Anemia Mukt Bharat (AMB) strategy was launched in April 2018 by the Ministry of Health and Family Welfare, Government of India. AMB has set a target of 3% reduction in the burden of anemia per year from 2018 to 2022. Hb estimation is the cornerstone for the diagnosis of anaemia which forms the basis for instituting preventive and therapeutic interventions and measuring the outcome of the management. The choice of methods for estimation of Hb depends on site of use clinical, community settings, availability of resources, validity of the device, the user technicians, health workers, nurses, and population including adults, blood donors, children, pregnant women. Appropriate treatment relies on accurate diagnosis at the point of care. So, there is a need to have a point of care diagnostic device that can detect anaemia with reasonable accuracy, especially in lower- and middle-income countries, where the probability of anaemia is high. Neogi et al. (2020) concluded from their study that detection of anaemia, HemoCue and TrueHb were comparable while for severe anaemia, TrueHb seemed to be a better and feasible POC device in the community settings.

HemoQR is a Hb detection test kit that consists of a detection strip and a mobile-based software application that enables immediate reporting of Hb levels and allows healthcare professionals to make decisions driven by the collected data. The technology is an amalgamation of HCS and Sahli's method of estimation of Hb concentration. It gives us accurate and instant results with a turnaround time (TAT) of 20 sec along with data collection and analytical report. It utilizes the HCS for POC measurement of Hb levels using the smartphone-based application, and it serves as a user-friendly and accurate method for the detection of anaemia. HemoQR is best suited for analysing Hb levels on spot under field conditions, which can help in the screening of anaemia in pregnant women, adolescent children, below poverty line population and adults with parasitic conditions. There is no requirement of external hardware, chemicals, modern equipped laboratory setting or skilled technicians skilled staff is required to perform the test. Also, the data would be captured online for better understanding of conditions at institutional level. These kits are very user friendly and can be used by any professional. From our previous study in sub district hospital setup, we got sensitivity, specificity and accuracy of 99.08 %, 98.92 % and 99.08% respectively by testing 200 individuals.

The results of this study were also similar with similar count of patients which and the sensitivity, specificity and accuracy were 92.06 %, 98.67 % and 95.75 % respectively using 400 samples. With this study in the PHC setup we can further confirm that though HemoQR which is based on the principle of colorimetric assay coupled with smartphone-based application does outperform the HCS and the Sahli's method of Hb estimation, making it an efficient cost-effective smart solution in the 21st century diagnostic world.

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