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Comparative study to evaluate the diagnostic performance of mission ultra Hb meter with haematology analyser i3 North Indian teaching hospital based study

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Abstract

Aim: To evaluate the diagnostic performance of Mission Ultra Hb Meter with Haematology Analyser i3 North Indian teaching hospital based study.

Methods: The present Prospective study was conducted in the Department of Surgery and Medicine and in collaboration with pathology department of SGT Medical College Hospital & Research Institute Budhera, Gurugram, Haryana, India, from June 2020 to May 2021. 500 patients' comprised 350 adults and 150 children for Hb estimation. Hb estimation was done simultaneously both by Mission Ultra Hb Meter and Haematology Analyser i3.

Result: A total of 500 samples were processed for hemoglobin estimation. Out of these 225 were males and 275 females. Mean haemoglobin concentration on Mission Ultra Hb Meter for adults and children were 10.88+/-2.36 and 10.22+/-2.51 respectively. Mean hemoglobin concentration by Hematology Analyzer i3 for adults and children were 10.98+/-2.15 and 10.52+/-2.52 respectively. This shows mean by Hematology Analyzer i3 is greater by 2.17% for adults and 3.06% for children. It takes less than 1 minute by Mission Ultra Hb Meter while 15- 20 minutes by HematologyAnalyzeri3. Mission Ultra Hb Meter requires almost negligible maintenance while automated analyzer regular maintenance. The mean (SD) hemoglobin level was 10.55 ± 0.52 and 10.75 ± 0.63 g/dl using Mission Ultra Hb Meter vs HematologyAnalyzeri3. There was a positive correlation (r = 0.51, P < 0.001) between hemoglobin levels by using Mission Ultra Hb Meter vs HematologyAnalyzer i3. The Bias of agreement was 0.4g/dl resulting to 95% correlation. We also observed that out of 500 patients tested 53 were true anemic when tested from HematologyAnalyzer i3. In comparison Mission Ultra Hb Meter provided a Sensitivity and Specificity of 92% and 96% in detection of anemia.

Conclusion: Hemoglobin concentration assessment by Mission Ultra Hb Meter using venous blood samples has shown acceptable agreement with Hematology Analyzeri3.

Keywords: Hb estimation, HematologyAnalyzer i3, Mission Ultra Hb Meter

Introduction

Assessment of hemoglobin is one of the most reliable indicators for anemia and is widely used to screen for anemic individuals and to evaluate responses to interventions [1]. Commonly used methods to estimate hemoglobin in a community setting are clinical examination for pallor, Sahil's method, World Health Organization color scale, and HemoCue. Unfortunately, these methods have several limitations, ranging from the lack of accuracy to complexity to high cost [2, 3]. There are various methods of hemoglobin estimation, invasive and noninvasive, of which the invasive type varies from simple paper scale reading to measurement by photometer, i.e., HemoCue and Sahil's method. The noninvasive types are the pulse oximetry, photoplethysmography, opt acoustic method, diffuse reflectance spectroscopy, and imaging-based technique, each with its own advantages and limitations. Accurate quantitative point of care diagnostic tests can confirm the diagnosis of anemia through measurement of a decreased amount of red blood cells or decreased hemoglobin concentration in the blood, but these are not suitable in most primary health-care settings with very low resources because they either require constant quality control by trained staff, use toxic or expensive reagents and consumables, or depend on electricity supply [4]. Diagnosis is thus often based on clinical signs alone such as conjunctival, palmar, and nail bed pallor. None of these signs, whether combined or singly, yield an acceptable diagnostic accuracy [5]. This leaves many cases undetected and untreated and also possesses the risk of unnecessary and potentially harmful blood transfusions, increasing the risk of

transmission of blood-borne pathogens, and wasting resources in case of misdiagnosed severe anemia [6]. There is a need for a simple screening method for the detection of anemia that can be used by public health workers in the field. Any method of screening or monitoring individuals for anemia at primary care level should be cheap, simple to operate, sturdy enough for field use, dependent neither on electricity nor batteries, and reasonably accurate. It should also use a minimum of materials that require regular replacement and should give immediate results. Hemoglobin concentration is routinely measured HematologyAnalyzeri3. Although these are very accurate and reliable, they are expensive, and problems of samples' transport to the laboratory may delay treatment [7]. In clinical measurement, comparison of a new measurement technique with an established one is often needed to see whether they agree sufficiently for the new to replace the old. Therefore, this study was aimed to compare two hemoglobin testing methods and to assess the utility of HematologyAnalyzer i3 against a Mission Ultra Hb Meter) and to ascertain whether Mission Ultra Hb Meter method could replace the traditional HematologyAnalyzer i3) for hemoglobin screening. Hence the present study was conducted with the objective to compare two methods for hemoglobin estimation.

Material and Methods

The present Prospective study was conducted in the Department of Surgery and Medicine and in collaboration with pathology department of SGT Medical College Hospital & Research Institute Budhera, Gurugram, Haryana India from June 2020 to May 2021, after taking the approval of the protocol review committee and institutional ethics committee. 500 patients included which comprised of 350 adults and 150 children for Hb estimation. Hb estimation was done simultaneously both by Mission Ultra Hb Meter and HematologyAnalyzeri3.

Methodology

Mission Ultra Hb Meter

The Mission Ultra Hb Meter (as given in Figure 1) testing system consists of a portable meter (reader) and disposable test strips containing reagent in a dry form for single purpose designed photometer. The device can be operated by two 1.5 Volt alkaline batteries. It comes with test strips stored in strips containers to maintain their integrity and shelf life. The device uses electrochemical method and the strips are filled with the chemical reagent system. A fresh fingertip capillary or venous blood specimen is applied to the sample tip of the test strip and automatically absorbed into the reaction cell where the reaction takes place. A transient electric current is formed during the reaction and the haemoglobin concentration is measured based on the electrical current detected by the meter. Then the result is shown in the centre of the meter display. The meter uses venous whole blood or whole blood anticoagulated with EDTA or heparin and or capillary blood for testing and the tests were performed as stated by the manufacturer.



Fig 1: Mission Ultra Hb Meter and Strips

HematologyAnalyzer i3

It is an automated blood cell counter for diagnostic use in clinical laboratories. It is an automated haematology analyzer with a 3-part differentiation that analyses many hematologic parameters including Hb and haematocrit levels. The analyzer has been proven to provide accurate and reliable results. The tests were performed according to manufacturer's recommendations.

The personnel involved in both the point-of-care testing with the portable meter and the laboratory staffs processing the automated haematology analyzer were blinded to either results, and all samples were analysed on the day of collection within 8hours.

Statistical analysis

The data from CRF were transferred to Microsoft excel sheet and were analyzed with appropriate software. The data was analyzed using independent sample t-test and correlation coefficient. P value < 0.05 was considered significant for all comparisons.

Results

A total of 500 samples were processed for hemoglobin estimation. Out of these 225 were males and 275 females (350 adults and 150 children). Mean hemoglobin concentration on Mission Ultra Hb Meter for adults and children were 10.88+/- 2.36 and 10.22+/- 2.51 respectively. Mean hemoglobin concentration by HematologyAnalyzer i3 for adults and children were 10.98+/- 2.15 and 10.52 +/-2.52 respectively. This shows mean by HematologyAnalyzer i3 is greater by 2.17% for adults and 3.06% for children.

This showed 2.62 % (overall) increase in results by manual method. Comparison of different parameters is.

It takes less than 1 minute by Mission Ultra Hb Meter while 15-20 minutes by HematologyAnalyzeri3. Mission Ultra requires negligible maintenance while Haematology analyser 3 requires proper maintenance. As in Table 1 and Figure 2

Table 1: Profile of the patients

Variable Number of patients	Mission Ultra Hb Meter = 500	HematologyAnalyzeri3=500
Mean Hb of Adults	10.88	10.98
Mean Hb of Children	10.22	10.52
Lowest Hb among Adults	3.50	4.20
Highest Hb among Adults	16.90	15.20
Lowest Hb among Children	4.10	4.60
Highest Hb among Children	19.0	19.10

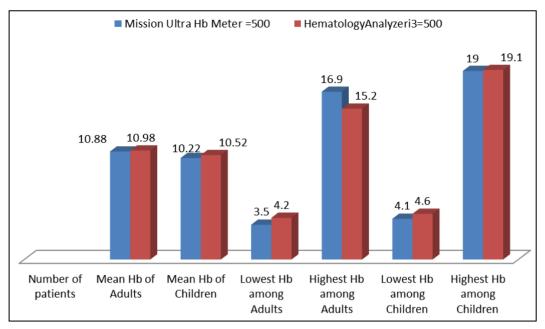


Fig 2: Patients Profile

Table 2: Hemoglobin level measured using Mission Ultra Hb Meter and automated Haematology Analyser i3 (g/dl)

Method of measurement	Mean ± SD	
Mission Ultra Hb Meter	10.55 ± 0.52	
HematologyAnalyzeri3	10.75 ± 0.63	

Table 3: Correlation, bias, and limits of agreement between hemoglobin level using Mission Ultra Hb Meter vs
HematologyAnalyzer 3

Comparison of methods	Correlation Coefficient	Bias ± SD (95%CI)
Mission Ultra Hb Meter vs HematologyAnalyzeri3	0.81	0.41 ± 0.11

Table 4: Sensitivity and Specificity for Anemia - Mission Ultra Hb Meter vs Hematology Analyzer 3

	Hematology Analyzer 3		Total
Mission Ultra Hb Meter	Positive	Negative	
Positive	49	18	67
Negative	04	429	433
Total	53	447	500

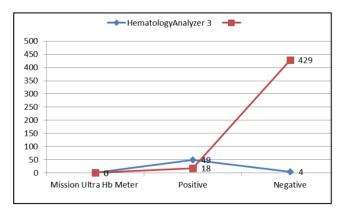


Fig 3: Sensitivity and specificity for Anemia - Mission Ultra Hb Meter vs Hematology Analyzer 3

The mean (SD) hemoglobin level was 10.55 (1.52) and 10.75 (1.63) g/dl using Mission Ultra Hb Meter vs Hematology Analyzer 3. (Table.2) Mission Ultra Hb Meter vs Hematology Analyzer i3 There was a positive correlation

(r = 0.81, P < 0.001) between hemoglobin levels by using Mission Ultra Hb Meter vs Hematology Analyzer i3. (Table.3). Out of 500 patients tested 53 were true anemic when tested from Hematology Analyzer i3. In comparison Mission Ultra Hb Meter gave true positive as 49 and true negative of 429 providing a Sensitivity and Specificity of 92% and 96% in detection of anemia. (Table 4 and Figure 3)

Discussion

Accurate determination of hemoglobin concentration is a common element in assessing the extent of anemia and making a decision regarding treatment. This decision should be made based on the reliable and rapidly assessed laboratory tests. The Mission Ultra Hb Meter is a portable device for measuring hemoglobin concentration and it requires very little staff training thus making it a very useful tool in resource-limited areas such as field conditions since it can easily be transported. In this study, we compared it with Hematology Analyzer i3 used in the laboratory. We found no significant differences in the hemoglobin concentrations determined by the two methods.

Recently Mission Ultra Hb Meter portable Haematology Analyser i3 using venous blood samples have been widely used for quick assessment of hemoglobin concentrations; especially in poor settings where skills and resources are limited

Studies showed that the results obtained by using Mission Ultra Hb Meter for hemoglobin assessment in adults were comparable to that of automated hematology analyzer as a standard.⁸ Bernard et al., found that the results of hemoglobin concentration among pregnant and nonpregnant populations using Mission Ultra Hb Meter were comparable to that of automated hematology analyzer and Cyanmethaemoglobin methods [9]. Other studies which were conducted in different settings and populations such as patients with gastrointestinal bleeding, surgical patients repeated measurement of one sample, urban general practice, neonates, patients undergoing aortic surgery in the theatre and blood donors recommended Mission Ultra Hb Meter for the hemoglobin estimation [10-17] Paiva et al. found that HemoCue was more appropriate for capillary compared to venous blood samples [18]. However, there was withinsubject variability of capillary blood hemoglobin values that might explain the unreliability of the method, and it has been shown that two capillary samples taken from different fingers of the same subjects had hemoglobin concentrations differing by/ more than two g/dL using the Mission Ultra Hb Meter [1].

In addition to the acceptable agreement of Mission Ultra Hb Meter with Hematology Analyzer i3 in this study, the Mission Ultra Hb Meter is simple to use, need minimum training, cheap, and gives an immediate result. Furthermore, it is useful in clinical and epidemiological settings where finger puncture allows capillary blood sampling as an easy technique which is less resource - intensive than vein puncture, and is more acceptable to patients and the community.

Conclusion

Hemoglobin concentration assessment by Mission Ultra Hb Meter using venous blood samples has shown acceptable agreement with Hematology Analyzeri3.

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