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INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI:10.21474/IJAR01/13918
DOI URL: <http://dx.doi.org/10.21474/IJAR01/13918>



RESEARCH ARTICLE

EVALUATION OF THE VALIDITY OF HEMOCUE HB 201+ FOR PREDONATION ASSESSMENT OF LOW AND HIGH HAEMOGLOBIN LEVELS IN BLOOD DONORS: ONE YEAR PROSPECTIVE STUDY IN BLOOD BANK OF GMC DODA

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Manuscript Info

Manuscript History

Received: 10 October 2021

Final Accepted: 14 November 2021

Published: December 2021

Key words:-

HemoCue Hb 201+, Automated HaematologyAnalyser, Blood Donors, Haemoglobin, Rapid Method

Abstract

Introduction: Predonation assessment of haemoglobin in blood donors is important to avoid unnecessary rejection of potential blood donors. Compared to the conventional screening methods for haemoglobin assessment the method to be used in blood banks needs to be rapid, sensitive and accurate for both low and high haemoglobin values.

Materials and methods: This was a prospective study conducted in blood bank of GMC Doda w.e.f 1st April 2020 to 31st March 2021. Finger prick samples were taken from 1214 potential blood donors and hemoglobin was estimated using HemoCue Hb 201+. Also venous samples of potential blood donors were obtained and run on automated haematologyanalysers. The values were compared. Male donors with haemoglobin in the range of 12.5g/dl -18.5g/dl and females with hemoglobin in the range of 12.5g/dl -16.5g/dl were considered fit for donation.

Results: We analyzed that haemoglobin levels measured by HemoCue Hb 201+ were higher than those measured by automated haematologyanalyser. We found a significant correlation between the standard method and HemoCue Hb 201+ for haemoglobin levels less than 12.5 g/dL. However the correlation was found to be less for high haemoglobin levels >18.5g/dl. Sixty percent of donors, who had haemoglobin levels higher than upper limit were unnecessarily rejected accounting for high deferral rate.

Conclusion: We concluded that HemoCue Hb 201+ was suitable for screening for low haemoglobin in blood donors. Male predominance among blood donors and topography of this particular area accounts for donors with haemoglobin values near upper limit which were falsely deferred on the basis of HemoCue Hb 201+. Also testing with this method was found to be expensive, so it was recommended that qualitative methods should be used for primary screening among blood donors and accurate quantitative methods to be used only when qualitative methods fail.

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Introduction:-

Pre donation assessment of hemoglobin is the most important test done on blood donors to determine their fitness for blood donation. The purpose of this test is to safeguard the potential donors to avoid taking blood from an anemic person. According to the standards mentioned by Drugs and Cosmetic Act of 1940, in order to accept a potential blood donor the haemoglobin levels should be more than 12.5 g/dL and hematocrit should be more than 38%¹. Also it is unsafe for the recipient to use blood obtained from donors with high haemoglobin levels >16.5 g/dl in females and >18.5g/dl in males since the blood can be of poor quality.

The methods conventionally used for hemoglobin estimation in blood banks are CuSO₄ gravimetric method and Hemoglobin colorimetric scale. Both of these methods are rapid, simple and inexpensive but they are qualitative or semiquantitative and can detect only low hemoglobin levels² and they are not suitable for detection of high hemoglobin levels.

Nowadays several methods of haemoglobin estimation are available which include; Cyanmethemoglobin method, Automated haematology analyser, Occlusion Spectroscopy and Pulse co-oximetry³.

However the ideal method to be used in blood banks should be rapid, sensitive, accurate for both high and low haemoglobin values, portable and with less expertise needed to run the test.

Aim:

This study was performed with the main aim to assess the diagnostic accuracy of a rapid, quantitative method (HemoCue Hb 201+) for detection of both low and high haemoglobin levels in potential blood donors.

Materials And Methods:-

This was a prospective study done in blood bank of GMC Doda w.e.f 1st April 2020 to 31st March 2021. A total of 1214 potential blood donors were found fit for donation in our blood bank during this time period.

Exclusion criteria for blood donors:

Age <18 and >60 years, pregnant and lactating females, history of febrile illness, history of covid -19 positive test or covid vaccination in last 28 days, paid donor, history of any serious illness, history of major surgical procedure, history of blood transfusion in last 12 months, history of any recombinant, killed or toxoid vaccine.

Finger prick(capillary blood) samples were taken from all these potential donors and hemoglobin estimation was done using (HemoCue Hb 201+) after discarding the first drop of blood. Also venous samples obtained by venipuncture were collected in EDTA tubes and samples were run on Automated HaematologyAnalyser (Erba H560) and the values of haemoglobin were compared. The criteria for acceptance of blood donors was taken as hemoglobin concentration within the range of 12.5 to 18.5 g/dl in males and 12.5 to 16.5g/dl in females.

Out of 1214 potential blood donors only 1198 were selected as fit donors with haemoglobin in the range of 12.5g/dl to 18.5g/dl.

The sensitivity, specificity, positive predictive values(PPV) and negative predictive values (NPV) and accuracy of (HemoCueHb201+) for both low and high haemoglobin levels were determined using the following formulae:

$$\text{Sensitivity} = \text{TP}/(\text{TP}+\text{FN})$$

$$\text{Specificity} = \text{TN}/(\text{TN}+\text{FP})$$

$$\text{PPV} = \text{TP}/(\text{TP}+\text{FP})$$

$$\text{NPV} = \text{TN}/(\text{TN}+\text{FN})$$

$$\text{Accuracy} = (\text{TP}+\text{TN})/\text{n}$$

TP is the number of blood donors who were correctly rejected on the basis of values obtained on HemoCue Hb 201+ .

FN is the number of blood donors who were falsely passed using HemoCue Hb 201+.

FP is the number of blood donors falsely rejected by using the HemoCue Hb 201+ measurement.

TN is the number of blood donors correctly passed for donation on the basis of the HemoCue Hb 201+

measurement.

n is the total number of samples.

Results:-

1214 potential blood donors were included in this study.

The values of haemoglobin obtained with HemoCue Hb 201+ were compared with the standard reference method (haematologyanalyser) and are summarised in Table I.

Table I:- Distribution of blood donors according to haemoglobin values obtained on HemoCue (Hb201+) using capillary and venous samples and on Erba H560.

	HemoCue Hb 201+ (capillary)	HemoCue Hb 201+ (venous)	Erba H560
Hb=12.5- 18.5g/dl	1193	1196	1193
Hb<12.5g/dl	11	10	17
Hb>18.5g/dl	10	08	04

HemoCue Hb 201+ showed that 11 potential blood donors had haemoglobin levels below 12.5 g/dL and were considered truly anaemic.

Taking into account high haemoglobin levels out of 10 potential blood donors who were rejected 06 were falsely rejected on basis of HemoCue Hb 201+.

Table II:- Distribution of blood donors on the basis of haemoglobin values obtained on automated haematologyanalyser.

	I (< 12.5g/dl)			II (12.5-18.5g/dl)			III (>18.5g/dl)		
	I	II	III	I	II	III	I	II	III
Capillary blood	11	6	0	0	1187	6	0	0	4
Venous blood	10	7	0	0	1189	4	0	0	4

Table III:- Diagnostic value of HemoCue Hb 201+ using capillary sample for low and high haemoglobin values in blood donors.

Haemoglobin values	Sensitivity	Specificity	PPV	NPV	Accuracy
< 12.5g/dl	64.71%	100.00%	100.00%	99.50%	99.51%
> 18.5g/dl	100.00%	99.50%	40.00%	100.00%	99.51%

Table IV:- Diagnostic value of HemoCue Hb 201+ using venous sample for low and high haemoglobin values in blood donors.

Haemoglobin values	Sensitivity	Specificity	PPV	NPV	Accuracy
< 12.5g/dl	58.82%	100.00%	100.00%	99.42%	99.42%
> 18.5g/dl	100.00%	99.67%	50.00%	100.00%	99.67%

Discussion:-

In our study we found that hemoglobin levels measured with HemoCue Hb 201+ were higher than venous hemoglobin levels measured by a standard method using Erba H560 automated haematologyanalyser. Similar results were obtained by Mendrone A Jr et al⁴ and Bahadur S et al⁵.

We found that as haemoglobin levels increased, the discrepancy between the haemoglobin levels measured with HemoCue Hb 201+ and the reference method also increased.

In present study we found that at low haemoglobin levels, there was a strong correlation between HemoCueHb 201+ and automated haematologyanalyser measurements and this correlation was similar to that found in other studies. In our study, the specificity of HemoCue Hb 201+ method for screening of haemoglobin levels lower than 12.5 g/dL was found to be 100% for both capillary and venous samples. In a study conducted by Akhtar K et al to

find out the prevalence of anaemia in potential blood donors using HemoCue Hb 201+, the sensitivity and specificity of the device was reported to be 94.1% and 95.2% respectively⁶. Tondon R et al conducted a study to assess different methods of haemoglobin estimation in blood donors and found the sensitivity and specificity of HemoCue to be 99.4% and 84.4% respectively⁷. We found that sensitivity of detecting Hb < 12.5g/dl was 64.71% for capillary samples and 58.82% for venous samples.

Taking into account sensitivity and specificity, the discriminating power for detecting anaemia was found to be greater for capillary samples than for venous samples.

Our results were comparable to results obtained by Hayedeh J. Shahshahani et al who reported sensitivity of HemoCue 201+ for capillary and venous samples as 79.4% and 64% respectively and specificity of 100% for both capillary and venous samples⁸.

We observed that as the haemoglobin level increased, the correlation between HemoCue and the standard method decreased, and at levels above 18.5g/dL, the correlation was not significant. While evaluating diagnostic value of the HemoCue Hb 201+ it was observed that for haemoglobin levels ≥ 18.5 g/dL, it had 100% sensitivity however its specificity and PPV were 99.50% and 40% for capillary samples and 99.67% and 50% for venous samples. Our results corresponded to the results reported by Hayedeh J. Shahshahani et al who reported sensitivity, specificity and PPV of HemoCue Hb 201+ for high haemoglobin levels as 100%, 79.8% and 31.7% for capillary and 96.3%, 85.7% and 38.8% for venous samples respectively⁸.

Predominance of male blood donors and high altitude in the area where study was conducted, accounted for the high haemoglobin levels in blood donors. This accounted for high deferral rate among the blood donors using HemoCue Hb 201+. This warrants the need for using qualitative methods of haemoglobin screening among blood donors. Accurate quantitative methods should be used when qualitative methods fail and when a portable and rapid Hb measurement is required for example in blood donation camps. However, the running cost of HemoCue is high compared to the traditional qualitative methods used.

Conclusion:-

We concluded that HemoCue Hb201+ combines the advantage of on-site testing with sufficient accuracy and rapidity. However a rapid haemoglobinometer should fulfill the basic criteria of economic and regulatory issues along with appropriate training and knowledge of staff regarding test requirements, performance and limitations. Also it was found that HemoCue Hb 201+ was suitable for screening of low haemoglobin levels better than higher haemoglobin levels, which explains why qualitative methods of haemoglobin assessment are still in use in bloodbanks.

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