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A prospective comparative study of estimation of hemoglobin using portable hemoglobinometer HemoCue and automated hematology analyzer in blood donors

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Abstract
Introduction: There are many methods available for predonation hemoglobin screening but there is no single method suitable for this purpose. To determine the accuracy of fingerstick hemoglobin assessment in blood donors, the performance of a portable hemoglobinometer (HemoCue Hb 301) was prospectively compared with that of an automated hematology analyzer (Horiba Pentra XLR).
Material and Method: 330 blood donor's capillary fingerprick, venous sample hemoglobin were measured by HemoCue Hb 301 and concurrent venous sample hemoglobin measured by automated hematology analyzer.
Results: Mean capillary hemoglobin using HemoCue Hb 301 was 13.60± 1.02 gm/dl which was more than venous hemoglobin using HemoCue Hb 301(13.39 ± 0.96 gm/dl) and both were higher than automated hematology analyzer venous hemoglobin values (13.13±1.01 gm/dl). The correlation coefficient between automated hematology analyzer and capillary HemoCue values was 0.98, between venous and capillary HemoCue was 0.99 and between automated hematology analyzer and venous HemoCue was 0.99. P value for all comparison group is < 0.0001. Fingerprick capillary hemoglobin value measured by HemoCue Hb 301 has only 1.53% false-pass rate.
Conclusions: Capillary fingerprick hemoglobin measured by HemoCue Hb 301 was slightly higher than venous hemoglobin value measured by an automated hematology analyzer. HemoCue Hb 301 is an appropriate and reliable screening method for pre-donation haemoglobin estimation for blood donors.

Keywords: Blood donor screening, Blood donation, HemoCue Hb 301, Capillary hemoglobin value

Introduction
Blood transfusion is an essential part of modern healthcare which saves millions of lives each year. Since blood is a unique resource for which an artificial substitute has yet to be found, blood donations are in great need. However sometimes blood donors cannot donate blood due to several reasons, the most common reason being low hemoglobin level of blood donors [1, 2].

The hemoglobin estimation of blood donors is the only laboratory test performed prior to blood donation. In India the minimum acceptable hemoglobin (Hb) value for blood donation is 12.5 g/dl for both male and female blood donors according to the Drugs and Cosmetic Act, 1940 rules 1945 amended from time to time [3].

Various methods of hemoglobin estimation have evolved over the period of years, from the simplest Hemoglobin test like tallquist chart method, to noninvasive screening methods like Pulse co-oximetry. Today we have various options like CuSO4 specific gravity, HemoCue and automated hematology analyzer methods for hemoglobin estimation in blood donors [4, 5]. Despite the availability of various methods for measuring donor hemoglobin, no single technique has emerged as the most suitable for hemoglobin testing in a blood donation setting [6].

Due to low cost, easy to use and rapid procedure, capillary blood collection with finger-prick method is widely used to determine hemoglobin level in blood donation setting [7]. The HemoCue method is gaining wide popularity over low cost CuSO4 specific gravity method

because it is portable and easy to use and gives accurate numerical hemoglobin value if it is standardized. The HemoCue is a portable, battery operated photometric device, being widely used as a point of care device for hemoglobin estimation in outdoor/indoor blood donation settings and critical care areas in health facilities. The gold standard method for hemoglobin estimation is cyanmethemoglobin method [8].

Hemoglobin screening of blood donors is very much essential because blood donation process should not harm the blood donor and it prevents anemic blood donor to donate blood. This also ensures that the patient who received packed red cell transfusion has optimum hemoglobin dose. So, it is very much necessary to screen the blood donor by appropriate hemoglobin estimation method. Since every single blood unit matters for a blood bank, hemoglobin estimation method should also be able to avoid unnecessary deferrals, should be smoothly incorporable into the operational practices and should have a reasonable cost[9].

The aim of this study is to compare capillary and venous hemoglobin values measured by the HemoCue with venous hemoglobin value measured by a fully automated hematology analyzer and to evaluate accuracy and reliability of HemoCue Hb 301 in measuring hemoglobin estimation value in blood donors who were accepted for blood donation in our blood bank.

Materials and Methods

This prospective study was conducted on the 330 blood donors who have donated blood in the blood bank, GMERS Medical College and General Hospital, Sola, Ahmedabad, Gujarat, from 1st March 2021 to 31st May 2021 over a period of three months. All blood donors in this study underwent a routine blood donor screening method including hemoglobin estimation by trained blood bank staff prior to blood donation. Informed consent was taken for blood donation.

Inclusion Criteria

Whole blood donors who came to blood bank during the time period of study and were declared medically fit to donate blood by qualified medical officer by standard blood donor screening criteria, having hemoglobin value ≥12.5 g/dL measured by HemoCue Hb 301.

Exclusion Criteria

Whole blood donors declared medically not fit to donate blood by a qualified medical officer by standard blood donor screening criteria having hemoglobin value <12.5 g/dL measured by HemoCue Hb 301.

Hemoglobin of each donor was measured by HemoCue Hb 301 using fingerprick capillary blood sample. Ring finger of the left hand was used for the prick. A finger prick was made using a sterile disposable lancet (Twist lancet, 30 G), after thorough cleaning of the finger with a spirit swab. The first drop was wiped off by dry cotton swab. A drop of blood was then drawn into a microcuvette by capillary action without applying any force on the finger. The blood filled microcuvette was placed in a given slot of the HemoCue Hb 301 photometer. After a few seconds (≤ 10 seconds), the hemoglobin reading appeared on the screen of the HemoCue Hb 301 device. Slot of the microcuvette was closed in between measurements.

Immediately following capillary sample testing in screening area, the donor was moved to a donor phlebotomy recliner chair in the blood donation area. Then two milliliters venous sample was collected from each donor before blood donation in EDTA vials, coated with dipotassium salt of EDTA. The EDTA blood sample was mixed well by 8–10 times gentle inversion. Hemoglobin was estimated in the venous sample using HemoCue Hb 301 immediately and in automated hematology analyzer (Horiba pentra XLR) as soon as possible within 30 minutes. Venous hemoglobin estimation was performed using the same HemoCue Hb 301 device which was used for the fingerprick capillary sample hemoglobin estimation. Since the volume of the capillary blood was small, it was not possible to measure hemoglobin from it in the automated hematology analyzer (Horiba pentra XLR). The hemoglobin value measured by the automated hematology analyzer (Horiba pentra XLR) was taken as reference value.

Results

Age group wise and gender wise distribution of blood donors (total 330) is shown in table 1.

Table 1: Age group wise and gender wise distribution of blood donors

Age group	Male	Female	Total
18-30	170 (94.98%)	9 (5.02%)	179 (54.24%)
31-40	91 (97.85 %)	2 (2.15%)	93 (28.18%)
41-50	47(97.92%)	1 (2.08%	48 (14.55)
51-60	10(100%)	0 (0%)	10 (3.03)
	318 (96.36 %)	12 (3.64 %)	330 (100%)

It can be seen from table 1 that 318 (96.36%) were male and 12 (3.64%) were female donors. Age group 18-30 years (54.24%) showed maximum number of blood donors while 51-60 years (3.03%) showed minimum number of blood donors. Among all the blood donors, the mean age of blood donors was 26 years.

Hemoglobin estimation value measured by automated hematology analyzer Horiba Pentra XLR was taken as a reference value. According to the reference value, two groups of blood donors were formed. One group of blood donors had hemoglobin value ≥ 12.5gm/dl and other group of blood donors had hemoglobin value < 12.5gm/dl. (Table 2)

Table 2: Distribution of blood donors in two groups according to hemoglobin estimation value by automated hematology analyzer.

	Group 1	Group 2	Total blood donors
Hemoglobin value	≥ 12.5 gm/dl	< 12.5gm/dl	330 (100%)
Number of donor	325 (98.47 %)	5 (1.53%)	

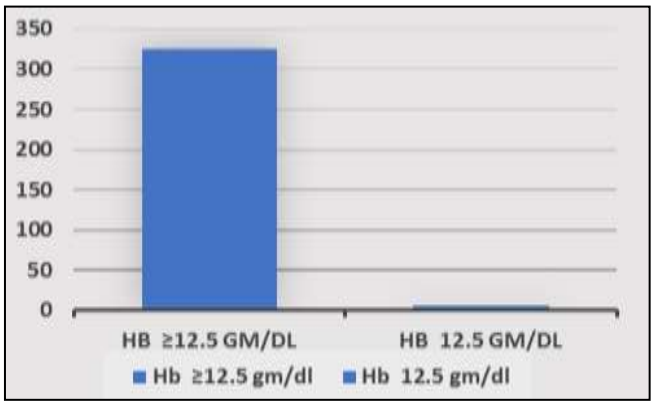

Fig 1: Two groups of donors according to hemoglobin value by automated hematology analyzer (cut off value 12.5 gm/dl)

It can be seen from table 2 that 325 (98.47%) donors had ≥12.5gm/dl hemoglobin while 5 (1.53%) donors had < 12.5gm/dl hemoglobin estimated by automated hematology analyzer Horiba Pentra XLR.

We estimated hemoglobin value using capillary and venous sample by HemoCue Hb301 and automated hematology analyzer Horiba Pentra XLR. Mean hemoglobin value, mean hemoglobin difference, correlation coefficient and P value were obtained by statistical analysis and paired comparison as shown in table 3.

Table 3: Paired comparison of capillary and venous sample hemoglobin determination by HemoCue Hb301 and automated hematology analyzer:

	Total No	Hb gm/dL (mean ± SD	Mean Difference (Hb gm/dl)	Correlation coefficient (r)	P value
Automated hematology analyzer hemoglobin VS Capillary HemoCue hemoglobin	330 330	13.13 ±1.01 13.60 ± 1.02	0.47	0.98	< 0.0001
Automated hematology analyzer hemoglobin VS Venous HemoCue hemoglobin	330 330	13.13 ±1.01 13.39 ± 0.96	0.26	00.99	< 0.0001
Venous HemoCue hemoglobin VS Capillary HemoCue hemoglobin	330 330	13.39 ± 0.96 13.60 ± 1.02	0.20	0.99	< 0.0001

It can be seen from table 3 that mean capillary hemoglobin using HemoCue Hb 301 was 13.60± 1.02 gm/dl, which was more than venous hemoglobin using HemoCue Hb 301(13.39 ± 0.96 gm/dl) and both were higher than automated hematology analyzer venous hemoglobin values (13.13±1.01 gm/dl). The mean hemoglobin difference between automated hematology analyzer and capillary HemoCue values was 0.47 gm/dl while between automated hematology analyzer and venous HemoCue was 0.26 gm/dl and between venous and capillary HemoCue was 0.20 gm/dl. The correlation coefficient between automated hematology analyzer and capillary HemoCue values was 0.98, between venous and capillary HemoCue was 0.99 and between automated hematology analyzer and venous HemoCue was 0.99. P value for all comparison group was < 0.0001.

Discussion

For blood collection, an appropriate hemoglobin screening method should be available to accept as many suitable donors as possible and to prevent any inappropriate deferrals. Unnecessary donor deferral (range from 0.4-16%) due to inaccurate hemoglobin estimation will lead to permanent blood donor loss [5].

In our study 318 (96.36%) were male and 12 (3.64%) were female donors. Female donors were fewer as compared to male donors, may be due to social customs and social misbelief that females cannot donate blood, so fewer number of female donors are willing for blood donation, even if female blood donors come for blood donation, they were mostly deferred due to high prevalence of anemia in Indian females.

In our study most common age group of blood donors was 18-30 years while 51-60 years was least common. 18-30 years age group comprised of young people having least comorbidities and least deferral as compared to 51-60 years age group which comprised of donors having more comorbidities and deferral.

In this study, the accuracy of a portable hemoglobinometer (HemoCue Hb 301) was evaluated by comparing capillary and venous hemoglobin values obtained using the hemoglobinometer (HemoCue Hb 301), to venous hemoglobin values obtained by an automated hematology analyzer (Horiba Pentra XLR).

We found that hemoglobin value of fingerprick (capillary) samples in blood donors using a HemoCue Hb 301 portable hemoglobinometer were slightly higher than values in concurrently drawn venous samples, which were closely correlated with venous hemoglobin results from an automated hematology analyzer. This may be because of the composition of a drop of blood obtained from the capillaries by fingerprick technique is not the same as blood obtained from a vessel by venipuncture. The fingerprick blood drop reflects the content of blood from various loop capillaries and small arterioles and venules in the finger. The fingerprick sample is also dependent on skin thickness, temperature of the skin, depth of penetration of the lancet and potential milking of the finger by the phlebotomist. Attention for training and periodic competency assessments of staff performing fingerprick hemoglobin assessments is a critical part of this evaluation of hemoglobin eligibility standards, with the intent of improving both the blood supply and the safety of blood donation.

Venous sampling provides a more reliable assessment of hemoglobin as it reflects the blood coursing through the veins, heart and arteries. Regulatory agencies do not specify the best technique for obtaining blood samples for hemoglobin testing to qualify individuals for blood donations. Each collection technique and testing method has its own variations and limitations. However, these differences should not be so significant as to compromise the donor's health and safety [10, 11, 12, 13].

Comparison of capillary hemoglobin values and venous hemoglobin values in various studies seen in Table 4.

Table 4: Comparison of capillary and venous hemoglobin values:

	Mean value of capillary hemoglobin (g/dL)	Mean value of venous hemoglobin (g/dL)
Present study	13.60±1.02	13.39±0.96
Patel *et al.* [14]	14.05±1.51	13.62 ± 1.23
Singh *et al.* [20]	14.32±1.41	14.40±1.54
Pi *et al.* [15].	13.5±1.02	13.26±0.72
Radtke *et al.* [16]	14.99±1.28 (male) 13.32±1.1 (female)	14.59±1.15 (male) 12.97±1.07 (female)
Darragh *et al.* [17]	13.1±0.2 (male) 12.1±0.2 (female)	14.1±0.7 (male) 12.8±0.6 (female)
Zeimann *et al.* [18]	15.59±1.08 (male) 13.73±1.01 (female)	15.38±0.87 (male) 13.64±0.91 (female)
Rudolf Oliveira *et al.* [19]	14.8±1.5	14.4±1.4

Findings from present study and various studies done by different authors are shown in table 4. Present study findings show capillary hemoglobin value is higher than venous hemoglobin value. Findings from various studies done by Singh *et al.*, Patel *et al.*, Pi *et al.* , Radtke *et al.*, Darragh *et al.*, Zeimann *et al.* and Rudolf Oliveira *et al.* are also similar as present study findings [14, 15, 16, 17, 18, 19, 20].

Previous studies in non-donor populations suggest that capillary HemoCue hemoglobin values are higher than

venous HemoCue hemoglobin values. However, these studies did not focus on healthy blood donors who are eligible for blood donation according to hemoglobin acceptance criteria [21].

Study done by Patel *et al*. [14] shows capillary hemoglobin values measured by HemoCue (14.05 ± 1.51 gm/dl) was higher than venous hemoglobin values measured by HemoCue (13.89 ± 1.31 gm/dl) and both were higher than venous hemoglobin values measured by automated hematology analyzer (13.62 ± 1.23 gm/dl). These findings are consistent with our study which show mean capillary hemoglobin measured by HemoCue Hb 301 was 13.60±1.02 gm/dl followed by venous hemoglobin measured by HemoCue Hb 301(13.39 ± 0.96 gm/dl) followed by venous hemoglobin values measured by automated hematology analyzer (13.13±1.01 gm/dl).

The hemoglobin value obtained by automated hematology analyzer was considered as gold standared [21]. Donor acceptance criteria for hemoglobin value is ≥ 12.5gm/dl as per Indian Drugs and Cosmetic Act, 1940 amendment from time to time [3]. Findings from table 2 shows that out of total 330 samples, 325 samples with Hb ≥12.5 g/dL and 5 samples with Hb < 12.5 g/dL measured by Horiba Pentra XLR automated hematology analyzer taken were as gold standard reference method. So, fingerprick capillary hemoglobin value measured by HemoCue Hb 301 has 1.53% false-pass rate. Foreign study done by Patel at el at USA has 6% false-pass rate [14] which is higher than our study. This may be because they used HemoCue Hb 201 which is an old version of HemoCue Hb 301. HemoCue Hb 301 is latest version which uses reagent free hemoglobin cuvette which has very less number of affecting factors like moisture which interferes with hemoglobin measurement done by HemoCue Hb 301 machine. We found this 1.53% false-pass rate to be operationally acceptable and within the range reported by other investigators [22].

These findings show hemoglobin measured by HemoCue Hb 301 is very much reliable and accurate.

Conclusion

The method used for hemoglobin screening of blood donors should be accurate, reliable and affording. The main purpose of the screening hemoglobin test is to prevent the development or worsening of anemia in blood donors as well as to reduce false rejection rate.

Fingerprick capillary hemoglobin value measured by HemoCue Hb 301 is slightly higher than automated hematology analyzer Horiba Pentra XLR.

Although hemoglobin measured by automated hematology analyzer is gold standard but it is not easy to transport, requires electricity and venous blood sample. While HemoCue Hb 301 is portable, easy to transport, battery operated instrument, fingerprick capillary blood sample required and easy to use with minimum staff training. Because of HemoCue Hb 301 accuracy, efficacy, utility, time taken, cost effectiveness and acceptable false rate in estimation of hemoglobin, we conclude that HemoCue Hb 301 is an appropriate and reliable screening method for pre-donation hemoglobin estimation for blood donors.

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