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Original Research Article

Haemoglobin measurement by point-of-care devices- a need of the hour: study conducted on antenatal females

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ABSTRACT

Background: Haemoglobin measurement in antenatal care can help in timely detection and treatment of anaemia, which is a major contributory factor to maternal mortality in developing countries. The transport of samples for haemoglobin assessment may delay the treatment, resulting in preventable deaths. Haemoglobin measurement by point of care testing (POCT) devices is easy, quick and less invasive. There are very few studies which compare the capillary blood haemoglobin using point of care devices with venous blood samples. This study was conducted to compare capillary blood haemoglobin using POCT device with venous blood haemoglobin using haematology analysers in antenatal Indian females.
Methods: One hundred pregnant women were recruited during their first trimester antenatal visits. Hemoglobin by finger prick capillary sample (POCT) was compared with haemoglobin of venous sample analysed by the haematology analyser (Beckman coulter) which was considered as gold standard. Intraclass correlation co-efficient based on Bland Altman analysis was computed using SPSS v21. A p value less than 0.05 was considered statistically significant.
Results: The intraclass correlation coefficient of 0.97 was recorded with central laboratory reference standard, with a mean difference of -0.481 gm% and -0.482 gm% by capillary and venous blood samples, respectively ($p<0.0001$).
Conclusions: A good agreement between capillary blood haemoglobin (POCT device) and venous blood (haematology analyser) was achieved.

Keywords: Capillary blood, Finger prick, Venous

INTRODUCTION

Haemoglobin (Hb) assessments are the most reliable indicator widely used to screen individuals for anaemia, to draw inferences about the iron status of populations and to evaluate responses to nutritional interventions.[1] Anaemia prevalence among pregnant women is 50% in India and contribute to significant maternal mortality and low birth weight.[2] Hb is measured routinely using venous blood by automated haematology analysers, such as those produced by Beckman coulter (California, United States) and Sysmex (Kobe, Japan) etc. Although these analysers are very accurate and reliable, they are expensive and require time for processing and that can lead to repeat visit for the report, which may contribute to loss to follow up and may delay treatment, resulting in preventable deaths.[3]

Implementation and importance of point-of-care testing (POCT) has steadily increased in recent times. The main feature of POCT is its access to diagnosis right at the out-patient department and in field setting where resources are limited and quick timely report help in early preventive measures and treatment. The advantages of POCT include low sample volumes, less invasive sample collection, elimination of long transport periods and

sample preparation procedures. The main disadvantage is the potentially higher costs. Also, POCT can be an additional task for non-laboratory trained staff members.

The efficiency of POCT training regarding proper execution of measurements and compliance with internal and external quality control requirements is critical.[4] These issues highlight the challenges in developing and introducing a legally binding and realizable POCT concept.[5]

This study was therefore conducted to generate data to support or refute, a POCT for Hb estimation. Limited data is available for Hb measurement from capillary blood samples on POCT devices in Indian population, especially among a vulnerable group, such as antenatal women.

METHODS

This cross-sectional, single centre study was conducted at VMMC and Safdarjung Hospital, New Delhi, for the period of two months, July 2021 to August 2021 in the department of pathology and lab medicine. One hundred pregnant women reporting for the Antenatal visit in their first trimester were recruited for the study.

Inclusion criteria

Pregnant women who visited the antenatal clinic in their first trimester irrespective of their parity were included in the study.

Exclusion criteria

Females in their second and third trimesters were excluded from the study.

Written informed consent was obtained from the subjects and the study was approved by the Institutional Ethical Committee (IEC) of VMMC and Safdarjung Hospital, New Delhi.

Two ml of venous blood samples were collected from each participant in EDTA anticoagulant vials. Finger prick was done in all the cases for capillary blood sampling. Venous blood samples were sent to central laboratory for haemoglobin measurement by Beckman coulter (California, USA).

Point of care testing (POCT) device Norma icon 3 (Norma diagnostics, Austria) was used to measure haemoglobin from capillary blood as well as venous blood samples. Norma Icon 3 is a small, 60 tests/hour impedance base haematology analyser. It has two modes, closed and open tube modes. Closed tube mode was used for haemoglobin measurement from venous blood samples, where machine takes the sample from the vacutainer. Open tube mode was used for capillary blood, where sampling tip sucks a drop of blood (~20 microlitre) from the glass slide and processes it.

Haemoglobin measurements were documented and compared with the central laboratory Beckman coulter which was used as a reference standard.

Statistical analysis

Intraclass correlation coefficient was calculated between haemoglobin measured by the gold standard Beckman coulter (venous sample), open tube mode (capillary sample) and close tube mode (venous sample) methods. Bland Altman plot was used to compare haemoglobin measured by Beckman coulter analyser with close tube and open tube methods. Univariate and multivariate linear regression was used to find out the relation of various methods of measuring hemoglobin with Beckman coulter.

The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of statistical package for social sciences (SPSS) software version 21.0. A p value of less than 0.05 was considered as statistically significant.

RESULTS

The mean age of pregnant women was 25.6±3.73 years old and ranged from 17 to 37 years old. Majority (48%) of pregnant women was in the age group of 26-36 years old.

Table 1: Demographic details of pregnant women.

Age group (in years)	Percentage
<20	15
20-26	35
26-36	48
>36	02

Table 2: Descriptive statistics of haemoglobin (gm/dl) of study subjects.

Haemoglobin (gm/dl)	Mean±SD	Median (25^{th}-75^{th} percentile)	Range
Open tube method (Norma open)	11.01±1.8	11 (9.975-11.925)	6.8-20.4
Close tube method (Norma close)	10.9±1.48	10.9 (10.175-11.925)	6.6-14.1
Beckman coulter	11.38±1.64	11.5 (10.375-12.425)	6.8-14.7

Table 3: Univariate linear regression to find out the relation of various methods of measuring hemoglobin with Beckman coulter.

Variables	Beta coefficient	Standard error	P value	Lower bound (95%)	Upper bound (95%)	Equation
Haemoglobin (gm/dl) Norma open	0.752	0.052	<0.0001	0.648	0.855	3.1+0.752*haemoglobin (gm/dl) Norma open
Haemoglobin (gm/dl) Norma close	1.078	0.025	<0.0001	1.028	1.128	-0.368+1.078*haemoglobin (gm/dl) Norma close

Table 4: Multivariate linear regression to find out the relation of various methods of measuring hemoglobin with Beckman coulter.

Haemoglobin (gm/dl) Beckman coulter	Beta coefficient	Standard error	P value	Lower bound (95%)	Upper bound (95%)
Haemoglobin (gm/dl) Norma open	0.050	0.036	0.173	-0.022	0.122
Haemoglobin (gm/dl) Norma close	0.844	0.092	<0.0001	0.662	1.026

Table 5: Intraclass correlation coefficient between haemoglobin measured by Beckman coulter, open tube (capillary) and close tube (venous).

Haemoglobin	Intraclass correlation coefficient (ICC)	95% confidence interval (CI)
Single measures	0.9247	0.8101 to 0.9626
Average measures	0.9736	0.9275 to 0.9872

Haemoglobin value measured with open and close tube method showed (POCT) an average of 11.01 gm/dl and 10.9 gm/dl respectively and an increased mean value for Beckman coulter.

Haemoglobin measurements from Beckman coulter and Norma icon 3 showed intraclass correlation coefficient (ICC) of 0.92 and 0.97 for single and average measures, indicating excellent agreement between the three methods (Table 2).

Table 6: Bland Altman plot of haemoglobin measured by Beckman coulter and capillary blood.

Hb (gm/dl)	Beckman coulter and open tube (capillary)
Sample size	100
Arithmetic mean	-0.481
95% CI	-0.5916 to -0.3704
p (H0: Mean=0)	<0.0001
Standard deviation	0.5572
Lower limit	-1.5731
95% CI	-1.7626 to -1.3835
Upper limit	0.6111
95% CI	0.4215 to 0.8006

Based on Bland Altman analysis, mean difference between Beckman coulter and open tube (capillary) was -0.481 (95% CI: -0.59 to -0.37), which was statistically significant with p value <0.0001 (Table 6).

Table 7: Bland Altman plot of haemoglobin measured by Beckman coulter and Norma close.

Hb (gm/dl)	Beckman coulter and close tube
Sample size	100
Arithmetic mean	-0.482
95% CI	-0.5595 to -0.4045
P (H0: Mean=0)	<0.0001
Standard deviation	0.3906
Lower limit	-1.2477
95% CI	-1.3806 to -1.1148
Upper limit	0.2837
95% CI	0.1508 to 0.4166

Mean difference between Beckman coulter and close tube was -0.482 (95% CI: -0.55 to -0.40) (Table 6) which was also statistically significant (p<0.0001).

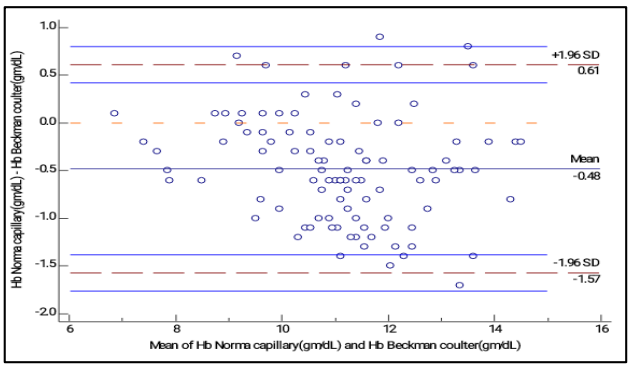

Figure 1: Bland Altman plot of haemoglobin measured by Beckman coulter and Norma capillary.

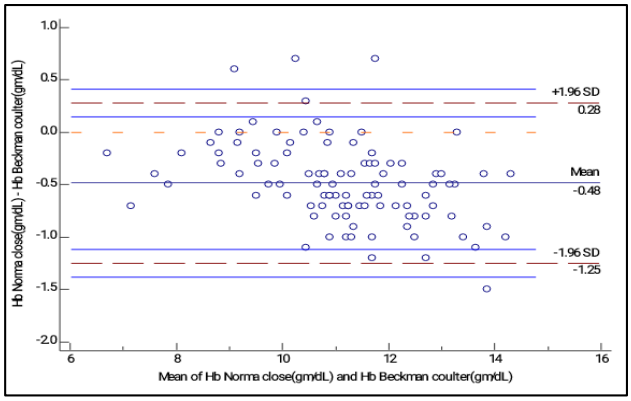

Figure 2: Bland Altman plot of haemoglobin measured by Beckman coulter and Norma close.

Limit of agreement (LoA) for open tube (capillary) was -1.573 to 0.611 (Figure 1) and LoA for close tube was -1.247 to 0.283 (Figure 2). Therefore, a good agreement was achieved between venous blood and capillary blood.

DISCUSSION

Point of care testing is emerging and more important in resource limited settings across developing countries. Data on point of care device use with capillary blood samples are limited as compared to venous blood samples. In our study we analysed capillary blood samples and venous blood samples**.** Capillary blood sample analysis was done on Norma icon 3 in open tube mode. Venous blood sample analysis was done in closed tube mode (Norma icon 3) and Beckman coulter analyser. Hemoglobin measurement from Beckman coulter was the gold standard in this study**.**

Hemoglobin measurement in antenatal care can help in timely detection and treatment of anemia, which is more valuable in developing countries with poor nutrition status. Ministry of Health and Family welfare under the Government of India launched 'anemia mukt Bharat' (anemia free India) program in March 2018 with POSHAN campaign to reduce anemia prevalence across India.[2,6]

We measured haemoglobin on point of care device and statistically compared its results with Beckman Coulter (gold standard in clinical laboratory). We analysed that our study results from POCT were statistically significant and the study results were also comparable with the results of reference standard. All the three measurements i.e. capillary blood using POCT, venous blood using POCT and venous blood using haematology analyser were in good agreement with each other as intraclass correlation coefficient (ICC) was 0.92 on single measure and 0.97 on multiple measure (≥0.9 is excellent relationship).[7]

The results showed that the limit of agreement (LoA) was in narrow range with closed tube method than the open tube/capillary Hb measurement. LoA for closed tube mode was -1.24 to 0.28 and for open tube mode was -1.57 to 0.61. Narrower the range of limit of agreement, more precise is the measurement. Similar results were obtained in study conducted by Arhamidolatabadi et al.[8] who studied haemoglobin and haematocrit by point of care device on ninety patients presenting to the emergency department in Tehran, Iran. They advocated that point of care device Mission® Plus Hb (ACON Laboratories, Inc. USA) was in good agreement (ICC: 0.98 for haemoglobin) with central laboratory Sysmex KX-21N™ (Sysmex, Norderstedt, Germany).[8] Another study by Maslow et al concluded that sole reliance on point of care testing devices was not advisable and different factors limit the haemoglobin measurement. They studied three POC devices haemoglobin measurement with Beckman coulter as reference standard.[9]

In a retrospective study conducted by Herman et al with point of care device EPOC® who compared the results with reference standard Sysmex XE-5000™, found that mean difference between the two was -0.268 (p=0.002).[10] In our study, mean difference with closed tube mode was -0.482 and it was -0.481 with open tube mode (p value <0.001). This showed that although the results were statistically significant, haemoglobin with point of care device was slightly higher than the reference standard. However, these results were with in clinical significant measurement of ±1 gm/dl. The measurements from point of care device are with certain bias and result benefits can outweighs the bias in remote resource limited settings.

Another study by Dolscheid-Pommerich et al showed a significant correlation between central laboratory Hb measurement (Hb-ZL) and POCT-Hb (System Rapidlab™ 1265) with p value <0.001 and r=0.96. The mean difference of measurement values was -0.44 gm/dl and standard deviation of 0.62.[11] Similar results were documented in our study with standard deviation of 0.39 for closed tube method and 0.55 for open tube method.

In study by Chutipongtanate et al, where author compared four different point of care devices with laboratory haemoglobin measurement concluded that all POCT devices significantly correlated with laboratory haemoglobin but at various degrees of correlation coefficient. They studied haemoglobin measurement on 35 patients in surgical intensive care unit.[12] Our study findings are in line with previous studies regarding agreement and we observed no trend in bias. POCT precision, accuracy and role in quick decision making has been studied in different devices, future studies are needed to focus on lower spectrum of measurements to find any association with critical cut off value.

Yadav et al conducted a study at primary health centre concluded that anemia screening can be done by POCT devices at community and individual level.[13] However, confirmation should be done with reference standards. In

this study mean difference was slightly lower for the two POCT devices (True Hb Hemometer -0.04 and HemoCue® Hb 301 System -0.09) as compared to mean difference in our study.

In our study we analysed both capillary and venous samples but mean difference was very similar via both the samples as compared to reference standard. In different studies, capillary Hb measurement is thought be on higher side as compared to venous blood because of different reasons like, haemoconcentration due to influence of posture and capillary blood is considered as a part of arterial blood.

Capillary blood Hb measurement is subject to multiple errors including depth of prick, skin thickness and temperature of skin. Neogi et al showed that point of care devices overestimated Hb by 2gm% in testing under cold weather conditions. They analysed capillary and venous blood samples and found that point of care device (True Hb), haemoglobin measurements reading were in agreement and comparable with each other. While for Hemocue haemoglobin measurements capillary blood samples yielded better results.[14]

Some studies indicate POCT use for time saving and in critical conditions. However regulatory guidelines need to be formed for generalized use and validity.

This study has some limitations. In our study we analysed measurement from one point of care device with reference standard and in outpatient department settings. More community/field setting studies need to be done for better assessment and decision making on use of POCT in India with geographical and climatic variation affecting measurement. Sensitivity and specificity should be measured in different subgroups along with agreement levels.

CONCLUSION

In this study we established a good agreement between POCT device and reference standard using both venous and capillary blood samples. Capillary blood samples Hb measurement is in comparison with venous blood samples. Large scale community studies are required to assess the validity for field use of POCT.

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