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Comparison of the accuracy of capillary hemoglobin estimation and venous hemoglobin estimation by two models of HemoCue against automated cell counter hemoglobin measurement

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Abstract:

BACKGROUND: HemoCue point of care devices has been extensively used in screening for anemia in blood banking. HemoCue can estimate hemoglobin (Hb) both from venous as well as capillary blood. However, the suitability of HemoCue Hb estimation in donor selection is unclear.

AIMS: The aims of this study were to evaluate variance of difference in Hb measurement in capillary HemoCue estimation as compared to venous HemoCue estimation from automated cell counter and to assess accuracy of two different HemoCue models (201 and 301) against automated cell counter Hb measurements in both capillary as well as venous blood.

MATERIALS AND METHODS: HemoCue 201 and 301 were evaluated by a comparison of methods study against Sysmex XP-100 three-part analyzer at a blood bank of a tertiary care hospital in Uttarakhand, India, in 2017. Assessment for anemia of 115 donors was done initially by capillary Hb by a convenience sampling to 2 instruments from 2 different models of HemoCue (total of 4 instruments). Venous blood collected was analyzed by Sysmex XP-100 and all HemoCue analyzers.

RESULTS: For capillary method, bias ranged from −0.97 to −0.37 g/dL, upper limit of agreement (LOA) ranged from 0.72 to −1.06 g/dL, and lower LOA ranged from −2.65 to −1.79 g/dL. For venous method, bias ranged from −0.03 to −0.24 g/dL, the upper LOA ranged from 0.81 to −1.07 g/dL, and lower LOA ranged from −1.04 to −0.57 g/dL. Thus, capillary HemoCue estimation exhibited greater bias as well as wider LOA. Variance of the differences from automated counter was significantly lower for venous HemoCue comparison compared to capillary HemoCue estimation ($P < 0.001$ for each instrument).

CONCLUSION: Errors in capillary sampling of blood show the extent to which preanalytical errors can influence results in point-of-care devices. We suggest augmentation of any blood bank-based Hb screening process based just on capillary sampling to be augmented by a properly selected venous sampling to reduce deferral for a false-positive screen of anemia.

Keywords:

Capillary, hemoglobin, HemoCue, variance, venous

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Introduction

Predonation hemoglobin (Hb) screening for blood donors is an essential procedure in blood banking. It is essential that a rapid, yet accurate method for Hb screening is used that can reject donors having low Hb to ensure donor health and maintain quality of blood components. Yet, it is also essential that prospective donors with adequate Hb not be falsely rejected so that supply of

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blood is not compromised. A rapid portable method is also essential for use in outdoor blood camps.

The HemoCue point of care devices has been extensively used in the screening for anemia in clinical situations.[1,2] This method has been shown superior to the copper sulfate method as a donor Hb screening method.[3,4] Although this method has been found satisfactory by some users, others have found HemoCue to result in a high number of inappropriate donor rejections.[5-7] HemoCue can estimate Hb both from venous as well as capillary blood. It is unclear Hb from which mode of blood collection was validated in some method comparison studies. Furthermore, the issue of instrument-to-instrument variability has also not been adequately reported.

Keeping in mind the above limitations in the existing literature, the present study was carried out in order to assess the accuracy of two different HemoCue models (model 201 and 301) against automated Hb measurements in both capillary as well as venous blood.

Materials and Methods

This study was initially conceived as a routine quality assessment of HemoCue instruments received and in use in our blood bank after preliminary validation. This study follows the Helsinki guidelines,[8] and we obtained our institutional ethical committee approval to publish our quality assessment findings.

Our blood bank has two instruments each of two HemoCue models 201 and 301 (hereafter, the individual instruments are referred to as a201, b201, a301, and b301, respectively). This study was carried out in the blood bank of a tertiary health care hospital in Uttarakhand, India, from February to March 2017. One hundred and fifteen prospective blood donors, after passing the medical checkup and found otherwise satisfactory according to Indian national regulatory guidelines,[9] were assessed for anemia initially by capillary blood Hb by a convenience sampling to two instruments from different models of HemoCue. Proper instructions of the user's manual were followed. Each donor was pricked once and the third and fourth drop of capillary blood was tested on two separate instruments after discarding initial two drops of blood. More than two instruments could not be tested on a single prick because of the difficulty in obtaining enough capillary blood for all four instruments after a single prick. Once found satisfactory, the donors were directed for donation. In such donors, venous blood was collected from the diversion pouch in K_2EDTA vials and sent for hematological analysis. In the case of prospective donors being found to have low Hb on predonation capillary Hb assessment, venous blood samples in K_2EDTA vials were taken to confirm or reject the findings, with the donor being temporarily deferred until the annulment of the capillary Hb report by an automated analyzer on the venous sample.

The venous blood thus collected was analyzed by Sysmex XP-100 three-part analyzer. Hb from the venous blood was also measured by all the HemoCue analyzers

Comparison between the different methods was carried out by the Bland–Altman limits of agreement.[10] The following comparisons were undertaken:

i. Separate comparisons of the capillary Hb estimation by the four different HemoCue instruments versus the automated Hb measurement by Sysmex XP-100
ii. Separate comparisons of the venous Hb estimation by the four different HemoCue instruments versus the automated Hb measurement by Sysmex XP-100. Before reporting the results, the differences between the different methods compared were visualized graphically by Bland–Altman plots and scatterplots
iii. Comparison of the variance of the differences between the capillary Hb estimation and the hematology analyzer readings to the variance of the differences between the venous Hb estimation by HemoCue and the hematology analyzer readings by the Levene's test.

All statistical analysis was carried out by the R statistical environment[11] and NCSS 11 statistical software (NCSS, LLC, Kaysville, Utah, USA).[12]

Results

The basic statistical descriptives of the Hb measurements by the different methods by the different instruments are given in Table 1. The mean difference along with the limits of agreement between the different instruments and the automated Hb estimate is given in Table 2. The above results show that there is significant under-reporting of Hb values by the capillary method of HemoCue relative to the automated counts. The bias is much reduced when Hb is measured from the venous sample by the HemoCue. The limits of agreement are also narrower (indicating lesser random error) for the venous estimation of Hb by HemoCue [Figure 1]. The variance of the differences from the automated counter is significantly lower for the venous HemoCue estimation as compared to the capillary HemoCue estimation ($P < 0.001$ for each instrument by the Levene's test).

The number of hemoglobin measurements which exceeded the acceptable total error of 7% for each mode of hemoglobin measurement for each instrument was also calculated. The number of such unacceptable errors in hemoglobin estimates by capillary sampling was

Table 1: The summary statistics of the reported hemoglobin by various methods by the instruments used

Method	Mean	SD	Median	Minimum	Maximum	1st quartile	3rd quartile	Count
Sysmex XP-100	15.5	1.3	15.6	10.8	18.5	14.8	16.4	115
a301-capillary method	15	1.4	15	11.2	18.1	14.2	15.9	57
a201-capillary method	14.6	1.1	14.7	12.3	17.2	13.8	15.4	55
b301-capillary method	15	1.3	15.1	11.1	18.2	14.3	15.6	58
b201-capillary method	14.6	1.4	14.7	10.1	17.5	13.8	15.5	58
a301-venous method	15.7	1.3	15.9	10.9	18	15	16.6	115
a201-venous method	15.4	1.4	15.6	10.1	17.8	14.6	16.2	115
b301-venous method	15.7	1.3	16	10.8	17.9	15.1	16.6	115
b201-venous method	15.4	1.4	15.7	10.1	18.1	14.8	16.3	115

SD = Standard deviation

Table 2: The mean difference and the Bland–Altman limits of agreement for the various HemoCue instruments and hemoglobin estimation method versus the Sysmex analyzer

	Parameter	Count	Value	95.0% LCL	95.0% UCL
a301 Capillary-Sysmex	Bias (difference)	57	−0.53	−0.73	−0.33
	Lower LOA	57	−2.00	−2.35	−1.66
	Upper LOA	57	0.95	0.60	1.29
b301 Capillary-Sysmex	Bias (difference)	58	−0.37	−0.56	−0.18
	Lower LOA	58	−1.79	−2.12	−1.46
	Upper LOA	58	1.06	0.73	1.39
a201 Capillary-Sysmex	Bias (difference)	55	−0.97	−1.20	−0.73
	Lower LOA	55	−2.65	−3.05	−2.25
	Upper LOA	55	0.72	0.32	1.12
b201 Capillary-Sysmex	Bias (difference)	58	−0.72	−0.92	−0.51
	Lower LOA	58	−2.23	−2.58	−1.88
	Upper LOA	58	0.80	0.45	1.15
a301 Venous-Sysmex	Bias (difference)	115	0.24	0.16	0.32
	Lower LOA	115	−0.57	−0.71	−0.44
	Upper LOA	115	1.06	0.93	1.19
b301 Venous-Sysmex	Bias (difference)	115	0.22	0.14	0.30
	Lower LOA	115	−0.62	−0.76	−0.48
	Upper LOA	115	1.07	0.93	1.20
a201 Venous-Sysmex	Bias (difference)	115	−0.11	−0.20	−0.03
	Lower LOA	115	−1.04	−1.18	−0.89
	Upper LOA	115	0.81	0.66	0.96
b201 Venous-Sysmex	Bias (difference)	115	−0.03	−0.11	0.05
	Lower LOA	115	−0.92	−1.07	−0.78
	Upper LOA	115	0.86	0.72	1.01

LCL = Lower confidence limit, UCL = Upper confidence limit, LOA = Limit of agreement

11 (out of 57, i.e., 19.30%) and 10 (out of 58, i.e., 17.24%) for the two instruments of HemoCue Model 301 and 23 (out of 55, i.e., 41.82%) and 21 (out of 58, i.e., 36.21%) for the two instruments of HemoCue model 201. The number of unacceptable errors in venous sampling was 1 (out of 115, i.e., 0.87%) and 1 (out of 115, i.e., 0.87%) for the two instruments of HemoCue model 301 and 2 (out of 115, i.e., 1.74%) and 1 (out of 115, i.e., 0.87%) for the two instruments of HemoCue model 201.

Discussion

The HemoCue devices with estimation of Hb from venous blood were found satisfactory in the present study, with acceptable shift and narrow limits of agreement. The Clinical Laboratory Improvement Amendments standards specify a total error of <7% for Hb estimation to be acceptable;[13] <2% of the measurements taken from venous blood in all the HemoCue instruments showed a >7% difference from the Sysmex analyzer.

The Hb estimations from capillary sampling in all the HemoCue instruments, however, are unsatisfactory for the blood bank, showing unacceptable bias as well as wide limits of agreement. About 17%–19% of the measurements taken by capillary sampling in HemoCue 301 and 36%–42% of the measurements taken by capillary sampling in HemoCue 201 showed difference of >7% compared to the Sysmex analyzer.

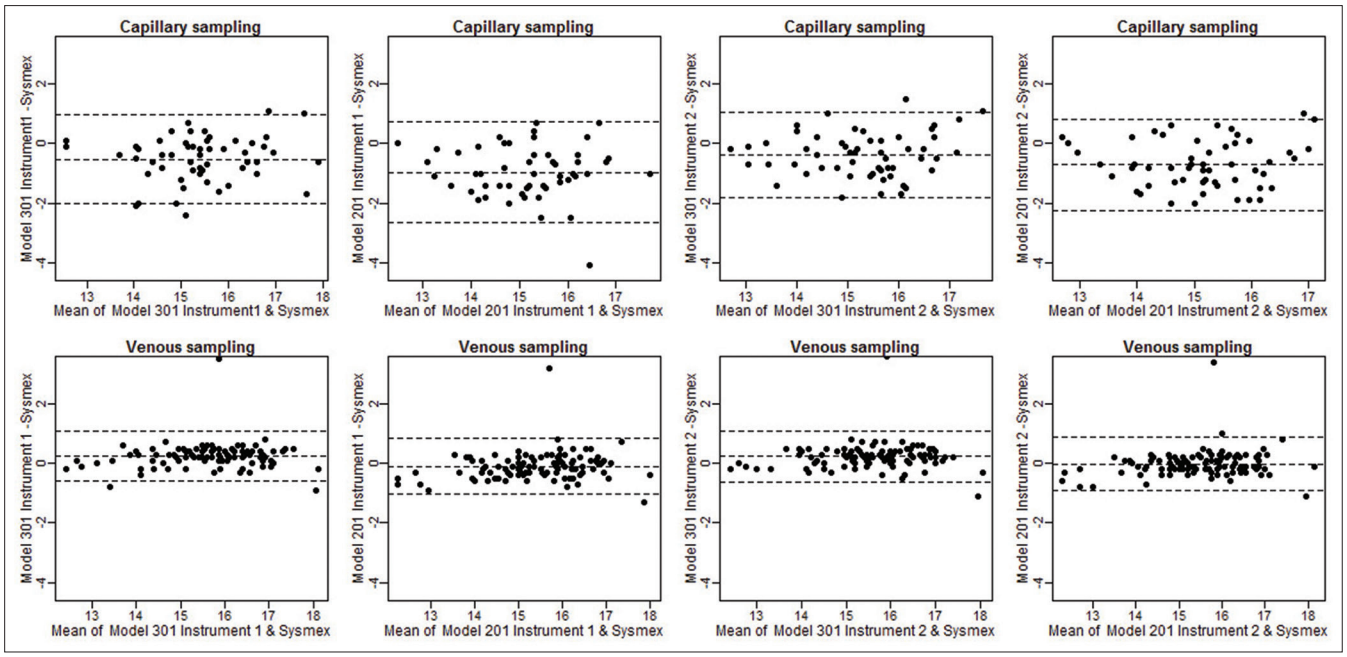

Figure 1: Variance of difference in HemoCue capillary versus venous hemoglobin measurement from automated counter hemoglobin measurement

If the findings in the present study can be slightly extrapolated, we would come to the inevitable conclusion that a lot of false-positive deferrals for anemia have taken place due to the negative bias of the capillary sampled HemoCue devices relative to Sysmex. This places a lot of burden on the blood supply. Therefore, we suggest that capillary sampled Hb from the HemoCue instruments be used with caution. Similar findings were found in a Spanish study, due to which they recommended a two-step strategy for Hb screening with the HemoCue.[5] Briefly, a two-step strategy entails re-testing of the venous blood if and when the prospective donor fails to have satisfactory Hb by capillary sampled blood. Since the venous sampled Hb by HemoCue is satisfactory for blood bank screening, this can be an ideal strategy in the present scenario. A criticism of this strategy is that an additional phlebotomy has to be done even before blood donation and may lead to increased donor noncompliance; however, this cost has to be weighed against the risk of loss of a donor anyway due to a false-positive screen of low Hb.

The errors in the capillary sampling of blood show the extent to which preanalytical errors can influence the results in point-of-care devices. The satisfactory results with venous sampling coupled with the unsatisfactory results with the capillary sampled Hb, supporting other studies,[5,7] show the difficulty in implementing a satisfactory point of care diagnostic or screening device. Even though the analytical quality of the devices seems to be satisfactory, preanalytical errors seem to be the primary determinants in the determination of quality or lack thereof of HemoCue devices. There may be variability in the amount of blood expressed, contamination with tissue fluids, errors in collection as well as selection of site for the lancet puncture, all of which may lead to significant errors in capillary blood sampling. Therefore, special attention needs to be directed toward training and proper use of the technique. However, the present evaluation used a single trained person for evaluation of Hb to reduce the error variability; the errors found in spite of such a precaution accentuates the problem of preanalytical errors even further.

This study was carried out in a blood bank setting; the unsatisfactoriness of capillary measurement for screening of anemia may or may not hold in a community setting. That evaluation needs to take the particular problem in question, and whether sensitivity or specificity or both of anemia diagnosis is more important. In a community setting needing a high sensitivity followed by confirmatory investigation and rapid treatment of anemia, a high sensitivity may take precedence over specificity, and capillary sampling may still be found adequate.

Conclusion

Hb estimation after venous sampling by HemoCue models 201 and 301 is accurate and suitable for Hb screening in the blood bank. Hb estimation after capillary sampling should be used more cautiously; we suggest augmentation of any blood bank-based Hb screening process based just on capillary sampling to be augmented by a properly selected venous sampling to reduce deferral for a false-positive screen of anemia.

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Conflicts of interest
There are no conflicts of interest.

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