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An alternate proficiency testing tool for a point of care hemoglobinometer: Hemocue

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Abstract
Background: Pre-donation hemoglobin screening, to determine donor fitness, can be done via different modalities [from crude copper sulphate solutions to point-of-care (POC) hemoglobinometers to automated cell counters]. Primary aim of the study was to develop and implement strategies for quality control for a Hemocue (a POC device) for the pre – donation hemoglobin screening.
Materials and Methods: A prospective observational study was done in properly stored 200 EDTA samples from April 2020 to October 2020. Daily two samples were analyzed using Hemocue and Automated hematology analyzer (Sysmex XN- 550) and compared by plotting their differences on Levey-Jennings (LJ) charts.
Results: 100 samples were >12.5gm/dL and 100 samples were <12.5 gm/dL. Mean Hb values were 13.54 ± 0.72 for sysmex > 12.5, 13.7± 0.75 for hemocue > 12.5 and 11.13 ± 0.96 for sysmex < 12.5, 11.37 ± 0.97 for hemocue < 12. No major outliers (differences outside 2 SD) were found in the LJ Plots.
Conclusion: Sample rerun could be used as a safer alternative to running costly commercial controls for screening of donor with POC hemoglobinometers.

Keywords: Hemocue, automated hematology analyser, hemoglobin

Introduction

Proper blood donor selection and meticulous pre-donation screening is one of the most important steps used to ensure blood safety [1]. The demand for blood has been never seen a fall in a country like ours with so many patients of thalassemia, chemotherapy undergoing patients, gynecology related issues and the most common of all, pregnant women. This mandate recruiting safe donors. The estimation of hemoglobin can be done through various modalities [2]. In spite of the importance of blood donor selection for blood safety, we need to consider that selection processes might have negative impacts on the blood supply, as many deferred donors might not return to donate again due to negative feelings resulting from their deferral [3].

Donors are selected firstly to ensure that they do not come to harm from giving their donation and secondly to ensure that their donation is unlikely to harm any recipient. Also, the reason for pre donation hemoglobin estimation also makes the blood product useful as the purpose of the transfusion is served.

There are several techniques for donor hemoglobin estimation with varying accuracy and reliability. Qualitative copper sulfate gravimetric method has been the archaic time-tested method that is still used in resource-constrained settings. Portable hemoglobinometers are modern quantitative devices that have been further modified to reagent-free cuvettes. Furthermore, noninvasive spectrophotometry has been introduced in some developed countries, mitigating pain to blood donor and eliminating risk of infection. However, each technique has an inherent variability that persists, notwithstanding the evolution of these devices. Hence, blood centers do need to pay attention to due validation of instrument, adherence to methodology and regular proficiency testing of the results [4].

The HemoCue Hb301 system determines the Hb concentration by measuring the absorbance of whole blood at an Hb/HbO2 isosbestic point. The device uses a double wavelength measuring method, 506 nm and 880 nm, for compensation of turbidity. The results are displayed numerically in g/Dl at the time of the measurement [5, 6].

This study proposes an alternative to the expensive commercial controls that need to be run everyday for the internal quality controls of the portable hemoglobinometers.

Aims and Objectives

The present study was undertaken to assess the use of sample re-runs as a proficiency testing tool for hemoglobin estimation between a point of care testing device (Hemocue) against the current gold standard (automated hematology analyzer) for the pre-donation hemoglobin screening of blood donors.

Materials and methods

1. Study Design

The present study is a prospective observational study of 200 samples done at A.D. Gorwala Blood Center, Central diagnostic laboratory of Shree Krishna Hospital and Pramukh Swami Medical College, Karamsad from April 2020 to October 2020. The freshly derived or properly stored 200 samples were divided into two groups: first 100 being those whose hemoglobin was >12.5 g/dl and the other group of 100 samples whose hemoglobin <12.5 g/dl. One sample with value of Hemoglobin less than 12.5 gm/dl and one with more than 12.5 gm/dl on automated cell counter-Sysmex XN-350/550, available at the Central Diagnostic Laboratory were selected daily. These samples were then run on Hemocue, available at the A. D. Gorwala Blood Bank and their values were noted. Bland Altman Analysis was done on the difference of values of both machines for both group of samples with 100 samples each. This analysis was done with the help of software SPSS 15.

2. Methodology

a. Estimation of Hemoglobin

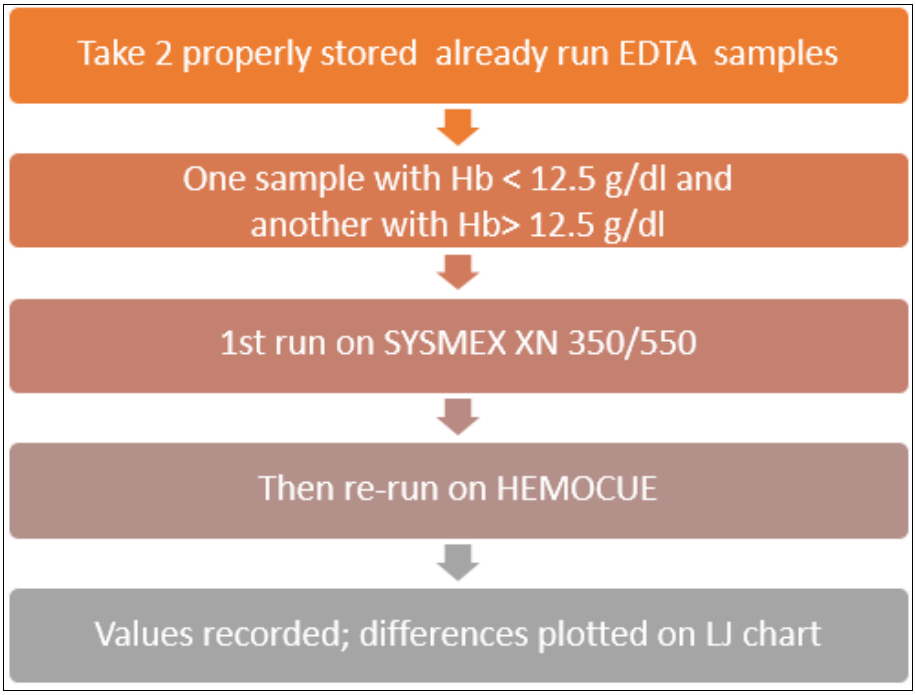


Fig 1: Estimation of Hemoglobin

b. Levey-Jennings Chart

The source of the samples we use for our daily Quality Control are two properly stored EDTA samples; one which has a value of more than 12.5 and the other one less than 12.5.

We plot the difference between the two values of the respective machines i.e., automated cell counter and HemoCue Hb301 on the Levey-Jennings chart.

These charts followed the Westgard rules.

c. Westguard rules

Table 1: The Westgard rules are as follows [7].

Rule	Criteria	Corrective Action
1_{2s}	One measurement exceeds 2 standard deviations either above or below the mean of the reference range.	Reject the reading. Repeat the QC
1_{3s}	One measurement exceeds 3 standard deviations either above or below the mean of the reference range.	Reject the reading. Repeat the QC
2_{2s}	2 consecutive measurements exceed 2 standard deviations of the reference range, and on the same side of the mean.	Reject the reading. Repeat the QC
10_{x}	10 consecutive measurements are on the same side of the mean.	Reject the reading. Repeat the QC

3. Data collection

The data of the sample runs were collected from the daily quality control register of hemocue which had logged in the results from the automated cell counter and the hemocue.

A table is made with headings of reading of sysmex (automated blood counter), reading of hemocue, the difference between the two and the signature of the Blood bank officer.

4. Data analysis

The difference between the two values for samples >12.5 g/dl and <12.5 g/dl obtained using both the machines is recorded. These values are then plotted on the Levey-Jennings graph after obtaining their mean and standard deviation.

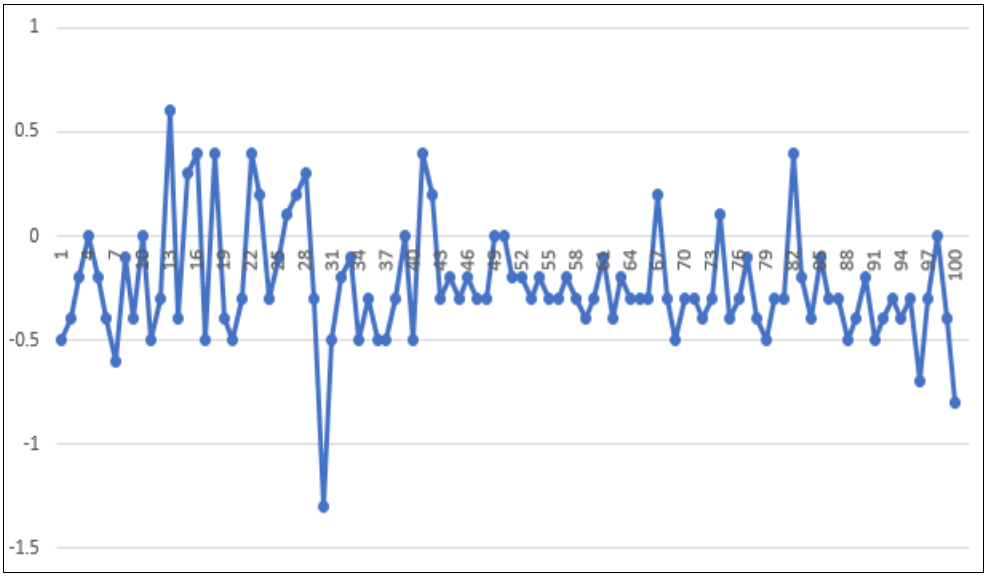
Results and Observations

The present study is a prospective observational study of 200 samples done at A.D. Gorwala Blood Center, Central diagnostic laboratory of Shree Krishna Hospital and Pramukh Swami Medical College, Karamsad. For initial analysis of the collected data, Mean and SD of both the methods and their difference was derived as listed in table.

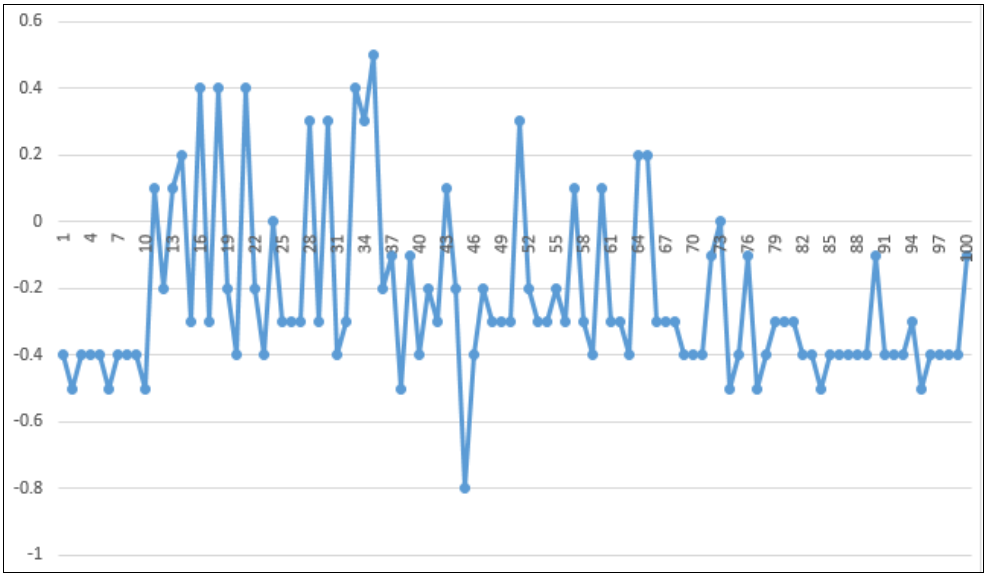
Table 2: Mean and SD of the Difference of Hemoglobin Values of both Machines.

		Mean	Standard Deviation
(>12.5 g/dl)	Sysmex	13.549	0.717951
	Hemocue	13.786	0.750356
(< 12.5 g/dl)	Sysmex	11.138	0.969171
	Hemocue	11.37	1.008527

The Levey-Jennings chart that we have plotted with the differences between the samples having Hb > 12.5 and <12.5 g/dl run on automated cell counter as well as Hemocue. The mean and SD were calculated using the first 20 samples and their differences.



Graph 1: Difference in the samples >12.5 g/dl



Graph 2: Difference in the samples <12.5 g/dl

Discussion

Importance of Levey-Jennings Chart Laboratory quality control is carried out to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results, in order to improve the quality of the results reported by the laboratory. Quality control is a measure of precision, or how well the measurement system reproduces the same result over time and under varying operating conditions.

The Levey-Jennings Chart is a graphical representation for plotting the quality control data to provide us with a visual indication whether a test is working well. The distance from the mean is measured in standard deviations. On the X-axis, the date of the sample run is taken and, on the Y-axis, the mean and standard deviations of the difference are plotted. As a sample is run the value of the difference is plotted on

the graph indicating how far the actual result was from the mean, which is the expected value of the difference. Lines can run across the graph at the mean, one or two standard deviations to either side of the mean. This makes the interpretation of how far the result was easier.

The hemoglobin value of donors is a very important aspect in determining the selection or deferral of a donor. Donors with hemoglobin more than 12.5 gm/dl are selected and those with hemoglobin <12.5 g/dl are deferred. There are many other criteria for the selection or deferral of a donor apart from hemoglobin, but hemoglobin has a mainstay in the selection of a donor. In any blood bank, Hemocue can very well replace the cell counter and also it is more cost effective as well as handy for blood donation camps [8, 9].

Westgard rules define specific performance limits for a particular assay (test) and can be used to detect both random as well as systematic errors. Westgard rules are programmed into automated analyzers to determine whether an analytical run should be rejected or accepted. These rules need to be applied carefully so that true errors are detected while false rejections (of valid results that are out of range) are reduced [10].

Conclusion

Despite the incongruities, hemocue can still be the test of choice for pre-donation Hemoglobin screening if the test is being done by trained staff following Standard Operating Procedures, especially in a resource limited country. Especially standalone blood banks and blood donation camps where resources are limited with many constrains, this can be used without much problem if quality check is done on daily basis. Hemocue showed good agreement with the cell counter in the current study. Hemocue, is a potential tool for donor screening and evaluation.

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