International Journal of Research in Health and Allied Sciences
Journal home page: www.ijrhas.com
Official Publication of "Society for Scientific Research and Studies" [Regd.]
ISSN: 2455-7803

ORIGINAL RESEARCH

Comparison of new strip based Point Of Care Testing Device (POCT) in the measurement of hemoglobin with hematology cell counter

Gauravi Jain[1], Arun Maity[2], Ajay Jain[3], Vivek Singhai[4], Anmol Bagaria[5]

[1]Professor & Head of Department of Prosthodontics, LN Medical College, Bhopal;
[2]Professor & Head of Department of Pathology, LN Medical College, Bhopal;
[3]Senior Medical Officer, Gandhi Medical College, Bhopal;
[4]BDS, MPH, PGDHHM, M.A (Psychology), PhD. (Hon.), Private Practitioner, Bhopal;
[5]BDS (Bharati Vidyapeeth Deemed to be University's Dental College & Hospital, Navi Mumbai), Private practitioner, Mumbai

***ABSTRACT*:**
Background: Hemoglobin estimation is an important screening test for identifying the anemia among patient population. Many methods are available for the screening of hemoglobin. How the new strip based Hemoglobin measurement system is working and to check reliability of the results. **Aims and Objectives:** To compare the new strip based Hemoglobin analyzer with Hematology Cell counter in respect accuracy, sensitivity, specificity and ease of usage. **Materials and Methods**: A prospective study is conducted utilizing 138 blood samples in laboratory which provide wide range of hemoglobin concentrations. Hematology Cell Counter (Mindray BC 5000, Mindray Corporation India) reference analyzer , Insta Hb (Strip based Point of Care Testing Device Manufactured by Inline K Healthcare LLP). **Results:** Out of 138 blood samples tested of where 78 were of male, 54 of females and 6 of children. Mean value of Insta Hbwas higher by 0.07 g/dl in males 0.38 d/dl in females an 0.38 g/dl in Children in comparison to Hematology analyzer which is not significant . In comparison to reference analyzer Insta Hb proved to be cost effective and have a sensitivity and specificity of more than 93%. **Conclusion:** New strip based hemoglobin measuring Point of care analyzer Insta Hb (Manufactured by Inline K Healthcare LLP) gives reliable results with high level of Sensitivity and specificity and can be a potential device for Anemia Screening, Low cost Laboratory alternative for Hemoglobin screening.
Key Words: Blood samples, Hematology analyzer, Insta Hb.

Received: 13 Jan, 2020 Revised: 29 Jan, 2020 Accepted: 30 Jan, 2020

Corresponding author: Dr. Arun Maity, Professor & Head of Department of Pathology, LN Medical College, Bhopal, M.P., India

This article may be cited as: Jain G, Maity A, Jain A, Singhai V, Bagaria A. Comparison of new strip based Point Of Care Testing Device (POCT) in the measurement of hemoglobin with hematology cell counter. Int J Res Health Allied Sci 2020; 6(1):52-55

INTRODUCTION:

Hemoglobin (Hb) is the vehicle molecule responsible for carrying oxygen from lungs to tissues. Hemoglobin was discovered in 1840. Over the years the estimation blood hemoglobin became an important domain in health care. Lack of Hemoglobin is resulting into a condition known as anemia and this critically affects the subject's oxygen carrying capacity. CBC and Hemoglobin are some of the first screening tests recommended by clinician for common ailment like fever or antenatal patients who regularly consult Gynecologists.

Complete blood cell count along with Hemoglobin provides key insights in to any infection or current anemia levels on the patients. In any hospital environment the number of antennal patients who do regular consultation needs to check of their hemoglobin on regular intervals. As cell counters are used for analysis of multiple parameters, an accurate, handy and alternate testing system for of only hemoglobin was as the subject of interest taken up.

Point of Care Testing:

The point of care testing is for the laboratory test that is performed close to patient, using easily operational devices. WHO in 1970"s had suggested that HB estimation to be made simple, cost effective with good technology so that field testing or primary care labs testing can done with ease. POCT testing is essential in situations like rural heal screening /blood donation camps where the analyzer can provide rapid test results with satisfactory accuracy which helps physicians to take appropriate decision on next level of treatment.

There are many invasive measurement techniques are available like Cyanmethemoglobin method (gold standard), Shali"s method, Color scale method and copper sulphate method.

The Cyanmethmoglobin method is a spectrophotometric method and is the gold standard for HB estimation. The advantage is this method is inexpensive and standard HiCN solution manufactured and assigned a concentration value according to precise criteria and reviewed by the international Council for the Standardization in Hematology at intervals. As this method uses Cyanide which is a hazardous waste, alternatives are always looked into.

WHO color scale is used in many stings where a drop of blood is absorbed by paper and the color is compared. As this method gives only a range and not give specific values more alternatives are explored.

Sahali's method is a dilution procedure adopted with N/10 HCL and values are reported through visual comparison to set standard and involves many variables like vision of technician, light source etcwhich challenges accuracy of result.

Hence we face multiple challenges in measurement like physiological, age, hydration status, smoking, pregnancy etc and it points to the need of a method which can minimize errors and cost effective. The device should be above to in low resource setting, low skill levels

MATERIALS AND METHODS

Insta Hb:

Recently we came across a new POCT device **Insta Hb** (Manufactured by Inline K Healthcare LLP) which is intended to be used for the quantitative determination of hemoglobin and calculated HCT (Hematocrit) in capillary, venous or arterial human whole blood by clinicians in primary care and field testing for screening of anemia. This portable meter works on reflectance photometry, that analyzes the intensity and color of light reflected from the reagent area of the test strip, ensuring quick results. This system can provide test results in less than 15 seconds and requires only a drop of blood for which a lancing device is also provided inside the pack. This device also comes with a memory of 1000 test results and data transfer options. The analyzers can be operated by normal AAA Alkaline batteries or rechargeable cells with optional charger which can be connected to mains are offered by the Manufacturer.

The prospective study was conducted on 200 blood samples which are from the patient population – Normal, suspected anemia and pregnant ladies. 2 ml of venous blood sample was collected in dipotassium EDTA tube. The tubes were placed on a mixed for 1-2 minutes before doing the testing in the Hematology cell Counter. Further the testing of the venous sample was done in the cell counter (Mindray BC 5000, Mindray CorporationIndia). Immediately the same samples were tested on the new POCT device Insta Hb (Manufactured by Inline K Healthcare LLP). Before doing the testing the meter set up for year, month, time format, time, measure in g/dL, mmol/L and g/dl and code chip from the strip pack in to the code port of the meter was completed. The strip is guided by arrow marks for insertion in to strip port so that user is guided well and no mistakes happen. One drop of sample (approx. less than 25 ul) was put into the specimen application area and results were on the display within 15 seconds and were noted.

STATISTICAL ANALYSIS

Statistical Analysis was conducted using SPSS 12.0 for Windows Microsoft , Seattle, WA, USA) Sensitivity, Specificity and Bias was calculated in comparison with reference method.

RESULTS

The gender distribution of 138 samples were 78 males (56%) 54 females (39%) and 6 children (4%) are available in Table 1. In addition to samples Hematology Analyzer was run on Hematology controls and Insta Hb (Manufactured by Inline K Healthcare LLP) was run with controls provided by the manufacturer are available in Table 2. Mean value of Insta Hb was higher by 0.07 g/dl in males 0.13 g/dl in females and 0.38g/dl in children compared to reference method which is insignificant and bias of < than 5%. In comparison to reference analyzer Insta Hb proved to be cost effective and have a sensitivity and specificity of more than 93%.

The mean Hemoglobin values obtained in Hematology analyzer is 11.95g/dl and on Insta Hb is 11.80g/dl and the bias is 0.75 g/dl which is well within the acceptable limits.

Table 1 Measurement of Hb measurement on Hematology analyzer (Mindray BC 5000, Mindray Corporation India) and Point of care analyzer Insta Hb (Manufactured by Inline K Healthcare LLP) Mean values.

Description	No.	Mean Value of samples Mindray BC 5000	Mean Value of POCT analyzer Insta Hb	Difference
Male	78	12.65 g /dl	12.58 g/dl	0.07
Female	54	7.63 g/dl	7.50 g/dl	0.13
Children	06	10.83 g/dl	11.22 g/dl	0.39

Table 2. Comparison of sensitivity, specificity and Bias obtained in comparison.

Test Results	Mindray BC 5000	Insta Hb
Mean +/- SD	11.96 +/- 1.01	11.80 +/- 1.02
Sensitivity	100	95.4
Specificity	100	93.2
Bias	0.02	1.2

DISCUSSION-

Previous studies comparing laboratory measurements and POCT measurements WBC count and C-reactive protein were reported satisfactory, but also significantly divergent results [6,7]. Ivaska et al. showed that WBC and CRP measured with a POCT device had sufficient analytical accuracy under local circumstances [6]. As a valid Hb measurement is a basic prerequisite in the first assessment, diagnosis and potentially therapy in an emergency patient, we opted for hemoglobin as a surrogate marker to evaluate the quality of the POCT concept at UKB. While in the other study comparing POCT-Hb measurement in postoperative critical-ill patients with perioperative Hb-ZL measurements, a good consistency of the correlation coefficients was shown, minor systematic deviations were found when comparing the measurement systems [8]. A further study also compared Hb measurements. However, this was done in a small collective and results cannot be compared [9].

Despite some deviations regarding the two types of measurements, the limits of agreement of the Bland-Altman plot indicate that the difference between POCT and Hb-ZL is comparatively small. However, some significant measurement deviations did occur. When examining these deviations more closely, it was found that only in 154 patients (i.e. 6% of the data) the difference exceeded >1g/dl. These findings demonstrate a good conformity between both measurement methods, which prooves the validity of the implemented POCT concept. When looking at clinically relevant subgroups, even smaller differences between the two methods may have an impact. During implementation as well as continuous quality control of POCT diagnosis in patient care, risks and benefits must be identified and minimized or maximized accordingly [10]. At UKB, all POCT quality control measures are the responsibility of the medical director of the central laboratory and thus by law equivalent to the quality control measures at the central laboratory. If a POCT device fails to pass the internal quality control, it is automatically disabled for the failed parameter and will only be released after successfully passing a follow-up control. The knowledge obtained from POCT error classifications has been included in our concept of training, follow-up training and troubleshooting [11].

With steadily decreasing resources and increasing costs through diagnosis, a scientific confirmation of the benefits of POCT in the decision making process in patient care has not been sufficiently examined to date [12]. Nevertheless, in many central emergency centers, POCT is the first step in the standardized emergency process in combination with a triage system. The triage system involves adequate categorization of priority levels immediately after patient admission at the emergency center [13]

CONCLUSION:

New strip based hemoglobin measuring Point of care analyzer Insta Hb (Manufactured by Inline K Healthcare LLP) gives high sensitivity and specificity to Hematology analyzer. This device can be a potential primary screening method and also an alternative for laboratory for Hemoglobin screening.

REFERENCES:

1. Radtke H, Polat G, Kalus U, Salama A, Kiesewetter H. hemoglobin screening in prospective blood doners comparison of different methods.
2. Zwart A, van Assendelft OW, Buss BS, England Jm, Lewis SM, Zijlstra WG, ICSH Recommendations for reference method for haemoglobinometry in human blood (ICSH Standards 1995(and specifications for international haemoglobinocyanamyde standard J Clin Pathol 1996:49:271-4
3. Manju Toppo, Dinesh Kumar Pal, Devendra Gour, Veeamelwani, Manju Dubey[1], Archna Mishra[2]Comparision of performance of Digital Hemoglobinometer over Automated Hematology Analyzer for hematology estimation and its user friendliness among pregnanat women inselected District hospitals of Madhya Pradesh.ijcm.org.in

4. AnukulN, Sombatmai R, Leetrakool N, Somphan P , Evaluation capillary hemoglobin measurement from portable Hemoglobinometer in blood donar screening.
5. Yadav k, Olivia,MJ, Ahamed F, Mandal M, Kant S. use of point of care Testing (POCT) in measurement of Hemoglobinm Indian J Comm health.
6. Ivaska L, Niemela ¨ J, Leino P, Mertsola J, Peltola V. Accuracy and feasibility of point-of-care white blood cell count and C-reactive protein measurements at the pediatric emergency department. PLoS One. 2015 Jun 2; 10(6):e0129920. doi: 10.1371/journal.pone.0129920 PMID: 26034987
7. Karon BS, Scott R, Burritt MF, Santrach PJ. Comparison of lactate values between point-of-care and central laboratory analyzers. Am J Clin Pathol. 2007 Jul; 128(1):168–71. doi: 10.1309/ HBQEFDPH34MKK5GP PMID: 17580286
8. Gehring H, Hornberger C, Dibbelt L, Rothsigkeit A, Gerlach K, Schumacher J et al. Accuracy of pointof-care-testing (POCT) for determining hemoglobin concentrations. Acta Anaesthesiol Scand. 2002 Sep; 46(8):980–6. PMID: 12190799
9. Yang ZW, Yang SH, Chen L, Qu J, Zhu J, Tang Z. Comparison of blood counts in venous, fingertip and arterial blood and their measurement variation. Clin Lab Haematol. 2001 Jun; 23(3):155–9. PMID: 11553055
10. O'Kane MJ, McManus P, McGowan N, Lynch PL. Quality error rates in point-of-care testing. Clin Chem. 2011 Sep; 57(9):1267–71. doi: 10.1373/clinchem.2011.164517 PMID: 21784764
11. Plebani M. Does POCT reduce the risk of error in laboratory testing? Clin Chim Acta. 2009 Jun; 404 (1):59–64. doi: 10.1016/j.cca.2009.03.014 PMID: 19298804
12. Pecoraro V, Germagnoli L, Banfi G. Point-of-care testing: where is the evidence? A systematic survey. Clin Chem Lab Med. 2014 Mar; 52(3):313–24. Review. doi: 10.1515/cclm-2013-0386 PMID: 24038608
13. Gra ¨ff I, Goldschmidt B, Glien P, Bogdanow M, Fimmers R, Hoeft A et al. The German Version of the Manchester Triage System and its quality criteria—first assessment of validity and reliability. PLoS One. 2014 Feb 24; 9(2):e88995. doi: 10.1371/journal.pone.0088995 PMID: 24586477