

Comparative Study of Hemoglobin Level of Blood Donors by CuSO₄ and Rapid HemoCue Method

Farah Anjum Sonia^{1*}, Marzia Mursafa², Subarna Saha³,
Jobaida Jannat⁴, Iffat Ara Akbar⁵, Atiar Rahman⁶

¹Assistant Professor, ³Medical Officer, ⁶Associate Professor, Department of Transfusion Medicine, Bangabandhu Sheikh Mujib Medical University (BSMMU), Shahbag, Dhaka, Bangladesh.

²Junior Consultant, Department of Transfusion Medicine, Monowara Hospital (Pvt.) Ltd, Dhaka, Bangladesh.

⁴Assistant Professor, Department of Transfusion Medicine, Rangpur Medical College, Rangpur, Bangladesh.

⁵Assistant Professor, Department of Transfusion Medicine, Shaheed Monsur Ali Medical College, Dhaka, Bangladesh.

ABSTRACT

Background: One of the responsibilities of Transfusion Medicine is to provide the safety to blood donors. Pre-donation hemoglobin screening is among the first and foremost tests done for blood donor selection with the main intention of preventing blood collection from an anemic donor. It is therefore essential, that there should be an accurate, reliable and minimum time required method for Hemoglobin determination. It is mandatory to screen a blood donor for Hemoglobin (Hb) or Hematocrit which should not be less than 12.5 g/dl or 38% Hct. There are various methods of hemoglobin estimation which vary from simple paper scale reading to take measurement by photometer, each with its own advantages and limitations. The copper sulfate (CuSO₄) specific gravity method is the traditional method being used for donor screening at many blood centers. Though a cheap and easy method, it does not provide an acceptable degree of accuracy. The HemoCue test system is a portable, battery-operated photometric device for rapid determination of hemoglobin. Worldwide Automated cell Counter method is used nowadays to estimate donor's hemoglobin. In Bangladesh the most common method which are used to estimate the donor's hemoglobin are CuSO₄ method and color scale method.

Method: It was a Cross-sectional comparative study of first time and repeated blood donors which were carried out at the Department of Transfusion Medicine, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, from July 2016 to December 2016 on 79 purposive voluntary, non-remunerated altruistic blood donors.

Results: This study results shows almost similar for CuSO₄ and HemoCue. Sensitivity of CuSO₄ 76.9%, Specificity of 97%. HemoCue was found to be less specific with specificity 95.5% and sensitivity 76.9%. The CuSO₄ screening test inappropriately passed 5/79 (6.3%) donors, while 06/79 (7.4%) donors were falsely deferred by HemoCue Method.

Conclusion: CuSO₄ method is cheap and gives accurate results, if strict quality control is applied. This method can be retained as the primary screening method; however, to save inappropriate deferrals, subsequent testing can be done with more precise method (i.e. HemoCue).

Keyword: Copper Sulphate Method, HemoCue (Rapid Method), Hemoglobin, Deferral.


*Correspondence to:

Dr. Farah Anjum Sonia,
Assistant Professor,
Department of Transfusion Medicine,
Bangabandhu Sheikh Mujib Medical University (BSMMU),
Shahbag, Dhaka, Bangladesh.

Article History:

Received: 12-06-2022, Revised: 08-07-2022, Accepted: 30-07-2022

Access this article online

Website: www.ijmrp.com	Quick Response code 
DOI: 10.21276/ijmrp.2022.8.4.001	

INTRODUCTION

The Hemoglobin estimation of blood donor is the only laboratory test performed prior to blood donation and is of paramount importance. Pre-donation Hemoglobin screening is used both to safeguard the health of potential donors and to ensure an adequate quality of blood products for recipients. The minimum acceptable Hemoglobin (Hb) is 12.5 g/dl or Haematocrit (Hct) of 38% for both males and females in Bangladesh.¹ Many people in our country are anaemic. So, selection of blood donors with

sufficient Hb depends on the method which we use for determination of Hb. The primary purpose of Hb screening is donor protection, preventing an anemic individual from exacerbating their condition with ill effects. The second purpose is to ensure the patient receives a minimum infused Hb dose per Red Blood Cell transfusion.^{2,3} Various methods of Hemoglobin estimation have evolved over the period of years, from the simplest Hb test, the Tallqvist method⁴ in which the color of blood

in blotting paper was compared with a color scale to measurement by photometer, Sahli's technique simple and cheap technique, the Copper-sulfate method in which a drop of whole blood dropped into a solution of CuSO₄ which has a given specific gravity, HemoCue which is a battery operated non-toxic reliable method, Automated analyzer which is accurate and reliable each with its own advantages and limitations. 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. Validity of these methods has to be evaluated before use and methods with sufficient sensitivity and specificity should be used in order not to expose blood donors and recipients to risk or to lose potential donors. Numerous studies have been done to evaluate the diagnostic value of these rapid methods for determining low Hemoglobin levels and anaemia.^{3,5,6} The goal of these studies is to select highly sensitive and accurate methods with very low false-deferral and false-pass rates. The main objective of the study is to compare the efficacy of the 2 common Hemoglobin estimation methods, namely, Specific Gravity Method using Copper Sulphate and HemoCue (rapid method) with automated method estimator in reporting the actual Hemoglobin levels of blood donors. In this study we have taken automated method as gold standard.

MATERIALS AND METHODS

It was a Cross-sectional comparative study of 79 blood donors' procedures which were carried out at the Department of Transfusion Medicine, BSMMU, Dhaka, after approval of protocol from IRB, from July 2016 to December 2016. Every donor's hemoglobin level was verified before the donation in 3 common methods of hemoglobin estimation. Procedure details and findings were recorded on specifically designed proforma. All the procedures were carried out by using following departmental Standard Operating procedures (SOP). Details of this study were explained to each donor who gave due consent before the procedure. After donor selection, according to inclusion and exclusion criteria, the procedures were done. Donors were made comfortable before starting the study.

Fig 1: Results of CuSO₄

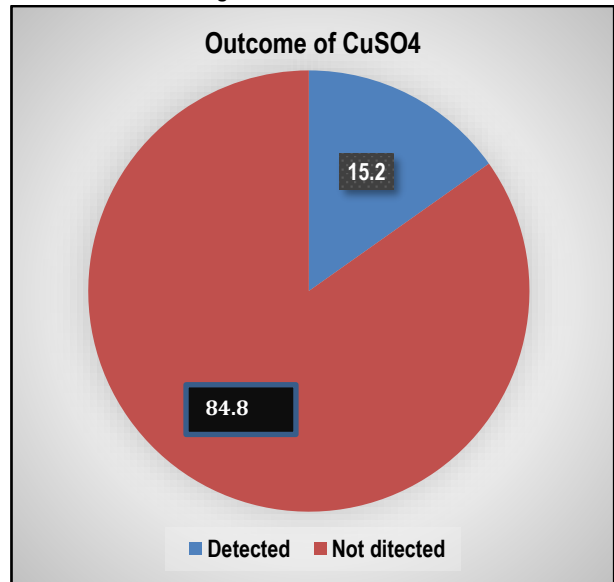


Fig 2: Results of HemoCue

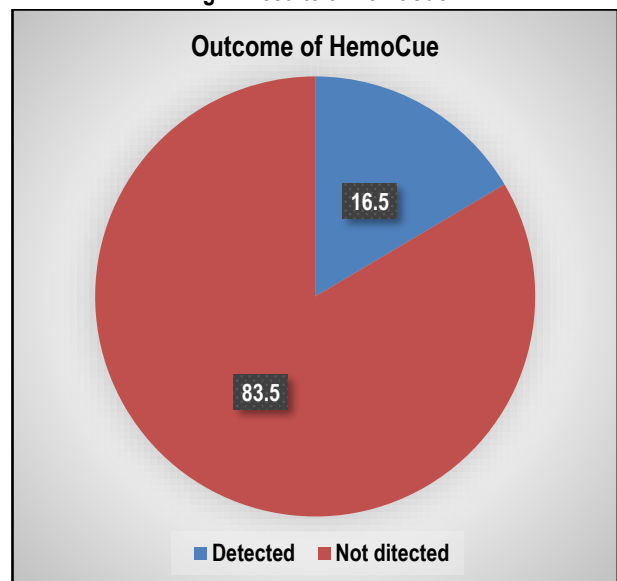


Table 1: Cross Tabulation of CuSO₄ and Automated Method

Cross tabulation of CuSO ₄ and Automated Method			Automated Method		Total
			Detected	Not detected	
CuSO ₄	Detected	Count	10	2	12
		% within CuSO ₄	83.3%	16.7%	100.0%
		% within Automated	76.9%	3.0%	15.2%
	Not detected	Count	3	64	67
		% within CuSO ₄	4.5%	95.5%	100.0%
		% within Automated	23.1%	97.0%	84.8%
Total	Count	13	66	79	
	% within CuSO ₄	15.2%	84.8%	100%	
	% within Automated	100.0%	100.0%	100.0%	

Table 2: Cross Tabulation of HemoCue and Automated Method

Cross tabulation of HemoCue and Automated Method			Automated Method		Total
			Detected	Not detected	
HomeCue	Detected	Count	10	3	13
		% within HemoCue	76.9%	23.1%	100.0%
		% within Automated	76.9%	4.5%	16.5%
	Not detected	Count	3	63	66
		% within HemoCue	4.5%	95.5%	100.0%
		% within Automated	23.1%	95.5%	83.5%
Total	Count		13	66	79
	% within HemoCue		16.5%	83.5%	100%
	% within Automated		100.0%	100.0%	100.0%

Table 3: Sensitivity and Specificity Analysis

Results	CuSO ₄	HemoCue
True Positive	76.9	76.9
True Negative	97.0	95.5
False Positive	3	4.5
False Negative	23.1	23.1
Sensitivity (%)	76.9	76.9
Specificity (%)	97.0	95.5
Likelihood Ratio	25.6	17.1

RESULTS

This study results shows almost similar for CuSO₄ and HemoCue. Sensitivity of CuSO₄ 76.9%, Specificity of 97%. HemoCue was found to be less specific with, Specificity 95.5%, Sensitivity 76.9%. The CuSO₄ screening test inappropriately passed 5/79(6.3%) donors, while 06/79 (7.4%) donors were falsely deferred by HemoCue Method. Different methods used in the present study are compared in [Table 3].

DISCUSSION

The Hb estimation of blood donor is the only laboratory test performed prior to blood donation and is of paramount importance. The main objective of our study was to compare the efficacy of the three common hemoglobin estimation methods, namely, CuSO₄ Method, HemoCue photometer and Automated Cell Counter in reporting the hemoglobin levels of blood donors. This prospective study was conducted on 79 random voluntary, non-remunerated altruistic blood donors over a period of 6 months. Copper Sulphate results were interpreted as pass or fail, digital readings were obtained for the other two methods. The sensitivity, specificity, positive and negative predictive values of each method was calculated. Hb screening by CuSO₄ is an inexpensive and convenient method to be used as for primary screening, supplemented with HemoCue for donors rejected by CuSO₄.

For blood collection an appropriate Hb screening method should be available so as to accept as many suitable donors as possible and to prevent any inappropriate deferrals. Any new method to be introduced for Hb screening should save time and expenditure and should be validated against major cell counters.

Performance characteristics in terms of sensitivity, specificity and PPV, NPV etc. are better with venous samples as compared to automated samples.

In this study CuSO₄ method inappropriately passed 6.3% of prospective donors, of which a majority (93.7%) were within the

threshold against the reference values, which is quite similar to the observations made by James et al.⁷ Similarly Boulton et al.⁸ observed more inappropriate passes by CuSO₄ Method with inappropriate passes being within 1.0 g/dl of the threshold for their gender. Average time required for CuSO₄ Method is 10.3 seconds. However, there are studies with contrasting results as well. This difference in results could be due to use of small sample size in our study. CuSO₄ has been a traditional way of donor Hb screening despite its limitations. To ensure correct results, CuSO₄ solution of accurate specific gravity should be used besides taking other technical precautions. The CuSO₄ Method has also been found to give inappropriate failures and significant number of such failed donors could be recovered with a revised Hb range or by using an alternative screening method.

HemoCue is an easy, rapid and reliable method of donor screening, however its use adds extra expense in a donor screening program if implemented as a primary Hb screening method. It is clear from our results that HemoCue is about 500 times costlier than the CuSO₄ method. Although the cost calculations are crude and various other factors viz. cost of lancets, other consumables, electricity charges etc. have not been included, yet implementing HemoCue for primary Hb screening would be beyond reach for many blood centers with limited resources. At the same time, the recovery of inappropriately deferred donors by HemoCue could indicate its usefulness as a secondary screening method.

The HemoCue hemoglobin photometer is a portable, battery-operated photometric device, being widely used as a point-of care device for hemoglobin estimation in mobile blood donations and critical care areas in health facilities. HemoCue also has an additional advantage over other photometric methods in that it incorporates a turbidity control, due to which more accurate results on lipaemic samples is obtained.

In our study the sensitivity of HemoCue was found to be 76.9% which is different to the results found by Sawant et al, Boulton et al, Chambers et al.⁸⁻¹⁰ But same sensitivity found in the CuSO₄. This is may be because of small sample size. HemoCue is simple to use, needs minimum training, and gives an immediate result. Average time required for HemoCue method is 37 seconds. It is useful in clinical and epidemiological settings where finger puncture allows capillary blood sampling as an easy technique which is less resource-intensive than vein puncture and is more acceptable to patients and the community.

In this study difference between these two methods were very minimal. HemoCue gave 7.4% false results against 6.3% by CuSO₄. It indicates CuSO₄ method gives accurate results, if strict quality control is applied. HemoCue is little bit expensive to be used as a primary screening method in an economically restricted country like Bangladesh.

CONCLUSION

The method used for Hb screening of blood donors should be reliable and affording. Hb screening by CuSO₄ still stands the test of time and it can be used as the primary screening method. Using HemoCue as the initial screening method could prove costly for some blood centers. The Hb level of donors rejected by CuSO₄ may be reassessed by HemoCue, to decide whether or not the donor needs to be actually deferred. This finding could be of value to blood centers with limited resources especially for camp donations where mass donor hemoglobin screening is carried out. HemoCue is a good method with high accuracy. Studies have found the HemoCue method to be more reliable, accurate, rapid, cheap, and easy to handle with no inter-observer variability as manual control is limited to on/off of the battery-operated system, compensates for turbidity and has high reproducibility. In a country like Bangladesh, where blood supply is always less than the requirement, this new technique (HemoCue) may be helpful to increase donor population, but cost-benefit ratio should be analyzed. Automated hematology analyzers have been found to have a higher precision than HemoCue. But this instrument is very expensive and cannot be used at health care facilities in rural areas because of the requirement of a laboratory.

CuSO₄ method is cheap and gives accurate results, if strict quality control is applied. This method can be retained as the primary screening method; however, to save inappropriate deferrals, subsequent testing can be done with more precise method (i.e. HemoCue).

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Source of Support: Nil. **Conflict of Interest:** None Declared.

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Cite this article as: Farah Anjum Sonia, Marzia Mursafa, Subarna Saha, Jobaida Jannat, Iffat Ara Akbar, Atiar Rahman. Comparative Study of Hemoglobin Level of Blood Donors by CuSO₄ and Rapid HemoCue Method. *Int J Med Res Prof.* 2022 July; 8(4): 1-4. DOI:10.21276/ijmrp.2022.8.4.001