Original Article

Deferral pattern in voluntary blood donors on basis of low hemoglobin and effect of application of digital hemoglobinometer on this pattern

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Abstract:

Background: One of the responsibilities of blood center is to provide safety to blood donors. 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. Most commonly applied method for hemoglobin estimation is copper sulphate method, but this method has chances of false acceptance as well as false deferral. In order to avoid this chance of error, digital hemoglobinometer is used. This study was planned to analyze effect of application of digital hemoglobinometer for detection of Hb on donors, who are deferred by copper sulphate method. **Materials and Methods:** Total 35,339 voluntary non renumareted altruistic donors were included in this study between the periods of September 2005 to July 2006. Total deferred donors were 8622 (24.39%) and donors deferred due to hemoglobin by copper sulphate method were 4391 (50.92%). Digital hemoglobinometer was applied on 3163 deferred donors (72.03%). Results of digital hemoglobinometer were validated by known controls. **Result:** Digital hemoglobinometer was applied on 3163 donors who were deferred by copper sulphate method. Out of this, donors accepted by digital hemoglobinometer were 1196 (37.01%). Total repeat donors were 629 (52.50%) and first time were 567 (47.40%). Male donors were 891 (74.44%) and females were 305 (25.50%). Donors deferred with digital hemoglobinometer were 2135, out of them 1097 (51.14%) were repeat, 1038 (48.38%) were first time, 1349 (60.79%) were male, 786 (34.47%) donors were female donors. Range of hemoglobin in deferred donors was 7.0 to 12.4 and in accepted donors 12.5 to 16.4. **Conclusion:** By the application of digital hemoglobinometer 37.81% donors were found hemoglobin >12.5 which were deferred with copper sulphate method and unnecessary deferral of donors can be reduced to a great extent. In country like India, where blood supply is always less than the requirement, this new technique may be helpful to increase donor population but cost benefit ratio should be analyzed.

Key words:

Copper sulphate, digital hemoglobinometer, hemoglobin

Access this article online

Website: www.ajts.org

DOI: 10.4103/0973-6247.98939

Quick Response Code:

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Introduction

Blood transfusion service is an integral part of the healthcare system throughout the world. The primary mission of any blood program for improving the safety of recipient and donor can only be achieved by constant and consistent effort of updating the standards of blood transfusion services.[1]

The donor should be in good health in order to avoid any untoward effect to donor or recipient. Therefore, every blood bank has to follow stringent criteria for blood donor acceptance. Hemoglobin (Hb) or hematocrit should be determined each time from the donor before donation. The Hb should not be less than 12.5 g/dL or 38% Hematocrit. The Hb may be measured by different methods. Most commonly applied method for Hb estimation for blood donation is copper sulphate ($CuSO_4$) method.[2]

The $CuSO_4$ method uses the principle that a drop of whole blood dropped into a solution of $CuSO_4$, which has a given specific gravity, will maintain its own density for approximately 15 seconds. The test solution should have a specific gravity of 1.053.[3] Errors in techniques in using the $CuSO_4$ method, for example, incorporation of air bubbles or the use of an inadequate height for dropping the blood, tend to result in underestimating the Hb concentration so that donors may be deferred unnecessarily. Low or high proteins in the donor may also lead to false results.[2]

Even though there are chances of error by $CuSO_4$ method, it is still the most widely used method in blood banks of India. There are other newer techniques also available, but there is insufficient evidence to support the utility of newer techniques like digital hemoglobinometer (Hemocue, Kuvettgatan 1, SE-262 71, Angelholm, Sweden). It is a photometric method based on determination of azide met-hemoglobin method.

Aim and Objective

This study was planned to evaluate the results of

Hb by CuSO4 test against the digital hemoglobinometer.

Materials and Methods

The study was conducted in a regional blood transfusion center of Western India. A total of 35,339 voluntary non-remunerated altruistic donors were prospectively included in this study between the period of September 2005 and July 2006. These blood donations were collected in outdoor blood drives, mobile vans and in-house. Total deferred donors were 8622 (24.39%) and donors deferred due to Hb by CuSO4 method were 4391 (50.92%) out of total donations. Digital hemoglobinometer (HemoCue 201)® was applied on all deferred donors except in some drives where it was not available. Hemocue was only used by doctors and nurses who were trained for the instrument, and standard operating procedure was followed stringently. The result was read within 60 s of the test. Total 3163 (72.03%) HemoCue tests were done to confirm the Hb results. The results of HemoCue were compared with CuSO4 results. When donor's Hb was found >12.5 gm% by HemoCue, he/she was accepted for donation. For validation of HemoCue results, control cuvettes provided by manufacturer of known values were tested periodically (every month) as quality control measure. Both Hb test methods, CuSO4 and HemoCue, were validated by hematology analyzer (cell counter). Only Ethylene diamine tetra acetic acid (EDTA) blood sample could be used in hematology analyzer for the validation, which was the limitation.

The results were evaluated by categorizing the donors on basis of gender and frequency of donation (first time or repeat).

Result

Digital hemoglobinometer (HemoCue) was applied on 3163 donors. Donors accepted by digital hemoglobinometer were 1196 (37.01%), who were deferred by CuSO4 method [Table 1]. Out of them 629 (52.50%) were repeat, 567 (47.40%) were first time; 891 (74.44%) males, 305 (25.50%) females. Donors deferred with digital hemoglobinometer were 2135; out of them 1097 (51.14%) were repeat, 1038 (48.38%) were first time; 1349 (60.79%) male donors, 786 (34.47%) female donors. Range of Hb in deferred donors was 7.0 to 12.4 and in accepted donors was 12.5 to 16.4 [Table 2].

Discussion

According to Food and Drug Cosmetic Act (1945), every prospective donor should have Hb of at least 12.5 g/dL, and it should be checked by any validated method. 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.[4] The CuSO4 gravimetric test has been the method of choice in every country for primary Hb screening of potential blood donors for many years. The use of capillary blood for Hb estimation by CuSO4 method of blood donor is controversial because of three aspects: its high dependence on performance with subsequently low reliability, its prolonging influences on donation procedure, and its low acceptance by donors when it is performed by finger prick. It is inexpensive, fast, and does not require venous sample. However, rigorous training and constant observation of staff is necessary. It doesn't give quantitative result of Hb and always has a chance of false acceptance and deferral. Early reports suggested that this method tended to give inappropriate failures, and a significant number of such failed donors could be recovered with revised Hb range or alternative method of screening.[4] On the other hand, rare cases in which plasma protein concentration is greatly raised, anemic donors may be accepted as normal by copper sulphate method, each extra g/dL of plasma protein being equivalent to 0.7 g/dL Hb. Falsely high positive results in CuSO4 sulphate method is also due to high white cell count.

At our center, a new alternative method of Hb screening was adopted in August 2005. By this method, undiluted blood is measured photometrically after conversion to hemoglobin azide (HiN3), a hemoglobin derivative, as a suitable alternative to hemiglobincyanide (HiCN). This system is named HemoCue.[5] This system was standardized against the International Committee for Standardization in Hematology (ICSH) method.[6]

Several studies performed on American blood donors have attested to the good reproducibility and accuracy of the HemoCue method.[7] According to Sawant *et al*.,[8] the sensitivity of three methods: Hemocue, Hb color scale, and Cyanmethemoglobin, are comparable and are 99%, 97%, and 96%, respectively. HemoCue method has been found to be easy in operation, less in training, and portable in size. It can be used in the field work and results are almost well comparable with standard reference methods (Zhao X, 2003).[9] In other studies Bhaskaram *et al*.[10] and Schenck H,[11] HemoCue and cyanmethemoglobin methods of Hb estimation were compared, and there are limitations expressing for both the methods in accurately estimating Hb. HemoCue is a good method of performing hemoglobin testing in blood donors, but there are many drawbacks with it such as the technique is very expensive, the procedure has to be validated regularly, and the procedure has to be standardized so that the chances of error can be minimized. It is important to carefully train the staff in the filling of the cuvettes, because air bubbles and fingerprints or blood on the cuvette face can give erroneous readings.

Table 1: Total blood donations and deferral from Sept 2005 to July 2006

Total donations	Total donors deferred (8622)		
	Deferred for other reasons	Deferred for Hb by CuSO4	Donors accepted by HemoCue
35,339	4459 (51.7%)	3163 (36.6%)	1196 (37.01%)

Table 2: Summary of donor acceptance and deferral after HemoCue application

Total HemoCue applied 3163	Accepted (1196, 37.01%)				Deferred (2135)			
	FT	R	Male	Female	FT	R	Male	Female
	567 (47.40%)	629 (52.50%)	891 (74.44%)	305 (25.50%)	1038 (48.38%)	1097 (51.14%)	1349 (60.79%)	786 (34.47%)

FT = First time, R = Repeat

By an another study, false pass and fail rates for women and men, respectively, were 11.2 and 6.3% (women) and 5.2 and 1.8% (men) for CuSO4; 1.9 and 3.7% (women) and 1.5 and 0.4% (men) for HemoCue; and 2.7 and 2.4% (women) and 1.8 and 0.2% (men) for a combined procedure that mimicked current practice of only testing if CuSO4 fails by HemoCue.[12] HemoCue shows excellent precision and lack of subjectivity as seen in CuSO4 method; this is a better method for evaluating potential blood donors.[13]

In the present study, total 3163 donors who were deferred by CuSO4, out of them 1196 (37.01%) donors were showing Hb >12.5 g/dL by the well-calibrated HemoCue method. Majority of them 891 (74.4%) were male donors and 629 (52%) were repeat donors. Chances of false deferral are more in male and repeat donors. On the other hand, majority of female donors those that were deferred by CuSO4 method, also were deferred by digital hemoglobinometer, showing that false deferral rate in female donors is less as compared to male donors. Large number of donors are falsely deferred because of less accurate method. In this study, gold standard method of Hb estimation, photometric cyanmethemoglobin, was not used, but HemoCue was calibrated with the known standard samples and results were comparable. Both Hb tests were validated by known blood samples tested by cell counter.

For Hb estimation, gold standard method photometric detection of cyanmethemoglobin requires venous blood samples to be collected. Taking a venous sample from each person before donation could prove unacceptable to donors, slow down the donation process, as well as increase the cost. Many studies have shown the excellent correlation between HemoCue and standard photometric methods in laboratory.[12] Because approximately 8 million donations are collected annually in India, even a small percentage of false accept or false defer at the Hb screening represent a large number of individuals. Therefore, any improvement in accuracy of Hb screening will be welcomed.

Conclusion

By the application of HemoCue, 37.01% donors were found hemoglobin >12.5 g/dL, which were deferred with CuSO4 method. Therefore, with this method, unnecessary deferral of donors can be reduced to a great extent. In a country like India, where blood supply is always less than the requirement, this new technique may be helpful to increase donor population, but cost–benefit ratio should be analyzed. Donor acceptance with HemoCue is more in repeat and male donors, so chances of false deferral are more with repeat and male donors.

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Cite this article as: Mathur A, Shah R, Shah P, Harimoorthy V, Choudhury N. Deferral pattern in voluntary blood donors on basis of low hemoglobin and effect of application of digital hemoglobinometer on this pattern. Asian J Transfus Sci 2012;6:179-81.

Source of Support: Nil, **Conflict of Interest:** None declared.