



ORIGINAL ARTICLE

Internal quality control of red cell concentrates in a regional blood center.

Muhammad Ali Rathore¹, Mommana Ali Rathore², Saadiya Mushtaq³, Inaam Qadir Javed Hashmi⁴, Abdur Rehman Hashmi⁵, Khadeeja Tul Kubra Hashmi⁶

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ABSTRACT... Objective: To assess the quality of the whole blood-derived red cell concentrates by measuring hematocrit. **Study Design:** Cross Sectional study. **Setting:** Regional Transfusion Center in Rawalpindi. **Period:** February to December 2019. **Material & Methods:** A total of 390 whole blood-derived red cell concentrates were included using a random sampling technique. These units were evaluated for hematocrit which is a hematological parameter using Sysmex Hematology Analyzer XP 100. The measurement of hematocrit was expressed as the mean range and standard deviation (mean \pm SD) using descriptive statistics. **Results:** A total of 390 whole blood-derived red cell concentrates were subjected to quality analysis by measuring the hematocrit. The mean range of hematocrit was found to be 68.4 ± 4.8 g/dL. The hematocrit of 98.7% units was in compliance with standard criteria according to the American Association of blood banks which suggested it to be less than 80%. **Conclusion:** The results of this study showed an optimum level of conformity of the quality of whole blood-derived Red Cell Concentrates with International Standards.

Key words: Hematocrits, Packed Red-Cell Volume, Quality Control.

INTRODUCTION

The therapeutic use of blood components is a vital health care resource in transfusion medicine. The processing of whole blood into its traditional labile components such as red blood cell concentrates (RCCs), platelet concentrates (PCs), fresh frozen plasma (FFP) and other plasma derived products facilitates optimal storage and appropriate use when required.¹ RCCs being very frequently used are indispensable components in clinical situations such as anemias, haemoglobinopathies, thalassemias, hemolytic anemias or chemotherapy to increase oxygen supply to the tissues.² The most common method used for the preparation of RCC is separation of plasma from whole blood by adding additive solution to red blood cells. Blood bank services encompassing hemovigilance with continuous monitoring of the quality of blood products is an important measure to ensure safe, effective and efficient transfusion services. Internal quality control (IQC) serves as a foundation of quality

management in a blood bank with the objective of providing efficacious blood components to a potential recipient.³

Being part of a good transfusion practices, comprehensive and continuous quality control allows recognition of compromised blood product quality which enables implementation of preventive measures to maximize the patient safety in the context of transfusion of blood components. In developing countries, quality control of blood products is not optimal due to fragmented and asynchronous blood transfusion services at provincial as well as national level.⁴ Therefore, this study was planned to evaluate the IQC of RCC as an important quality parameter of vital importance.

MATERIAL & METHODS

A cross-sectional study was conducted at Armed Forces Institute of Transfusion (AFIT) from February to December 2019.

1. MBBS, FCPS (Virology), Assistant Professor Pathology, Armed Forces Institute of Transfusion (AFIT), Sher Khan Road, Rawalpindi.

2. MBBS, M.Phil (Community Medicine), Armed Forces Institute of Transfusion (AFIT), Sher Khan Road, Rawalpindi.

3. MBBS, FCPS (Virology), Assistant Professor Pathology, Laboratory, Combined Military Hospital (CMH) Lahore.

4. MBBS, DC Path, M.Phil Microbiology FCPS Microbiology, Professor Pathology, CMH Kharian Medical College (CKMC) Kharian Cantt.

5. MBBS, Medical Officer Pathology, CMH Kharian Medical College, Kharian.

6. MBBS, DPT, House Officer, Benazir Bhutto Hospital (BBH)/ Rawalpindi Medical University (RMU) Rawalpindi.

Correspondence Address:

Dr. Muhammad Ali Rathore
Department of Pathology
Armed Forces Institute of Transfusion (AFIT),
Sher Khan Road, Rawalpindi.
robert50pk@yahoo.com

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Study protocol was approved by the Institutional Ethics Review Board vide Certificate No. AFIT-ERC-19-006. The whole blood units were collected into sterile triplet blood bags (Terumo, Vietnam) containing 63mL Citrate Phosphate Dextrose Adenine-1 (CPDA-1) anticoagulant. Inclusion criteria consisted of RCCs that were screened and found to be negative for markers of transfusion transmissible infections including HBsAg, anti-HCV, anti-HIV, anti-TP, whereas hemolyzed, FFP rich units and those having volume less than 500 mL were excluded. The sample size was calculated using Epi software with 95% confidence interval, margin of error 5% and anticipated frequency of 52% which calculated a sample size of 390 RCCs to be included in the study using simple random sampling technique. Within 6 hours of collection, whole blood was processed by centrifugation into packed red blood cells at 1700 revolutions per minute (RPM) for 4 minutes and at a temperature of 22° C in a cryofuge. Determination of hematological parameter comprising hematocrit (hct) was performed using Sysmex Hematology Analyzer (XP 100) in line with standards for quality control set by American Association of Blood Banks (AABB) [Table-I].⁵

Component	Parameter	AABB Criteria
Red cell concentrate	Hematocrit	<80% in units tested

Table-I. American association of blood bank quality control standards.

Data analysis was carried out using SPSS version 23.0 to obtain mean range, standard deviation and frequency by applying descriptive statistics.

RESULTS

A total of 390 whole blood derived RCCs were tested for IQC. The mean HCT detected was 68.4 ± 4.8 g/dl. Hematocrit of 385 bags out of 390 (98.7%) was in conformance with the mandated AABB standards with the exception of only 5 bags (1.3%) that had hct more than 80% [Table-II].

Variables	Hematocrit
Mean± SD g/dl	68.4 ± 4.8 g/dl
Range g/dl	51.4-96.7 g/dl
Result	
Units fulfilling AABB criteria	385 (98.7%)
Units not fulfilling AABB criteria	5 (1.3%)

Table-II. Quality control results of red cell concentrates.

DISCUSSION

Internal quality control of blood products ensures safe and efficient transfusion of blood products. Therefore, periodic testing of blood components is paramount to check the efficacy of transfusions done in clinical settings. Transfusion services employ quality control procedures to ensure viability and efficacy of blood products which may results in safe transfusion practices. IQC guarantees the effectiveness of blood bank work and results which may reduce the transfusion associated risks and consequently encourage to improve the production techniques. RCCs are very frequently used blood component, and therefore continuous monitoring of hematological parameters is essential to ensure their maximum safety, efficacy and quality.³ In developing countries, IQC testing is not being implemented in all blood banks and there is a need for periodic QC testing. The current study was conducted to analyze the hct of whole blood derived RCC (n=390). In our products, mean HCT was 68.4 g/dl which met the recommended criteria set by American Association of Blood Banks. There is no lower limit for hematocrit according to the established guidelines.⁵ These findings were consistent with a study conducted in a blood bank of tertiary care hospital from Southern Pakistan which demonstrated mean range of HCT as 69.5g/dl.⁶ Another study from Canada illustrated HCT range of packed red cells from 59.5 to 64.8% which is comparable to our findings. However, RBCs met the in-vitro quality control guidelines set by Canadian Standards.⁷ A study conducted at Lome showed 43.13% units met levels of hct which was discordant with the present investigation.⁸ Quality assessment of red blood cells analyzed according to European criteria in a study from India illustrated HCT range as 54% which is in sharp contrast with our quality

data.⁹ The small proportion of RCC units (1.3%) had HCT >80% in our study which might be due to faulty procedures. High hematocrit increases blood viscosity which results in thrombosis. Nevertheless, various contributing factors such as characteristics of donor population, storage conditions, blood collection, additive solutions and blood products manipulation lead to variability in quality markers.^{10,11}

To conclude, RCCs being produced in our setting are of good quality and compliant with international standards. Nevertheless, quality indicators should be monitored periodically in all segments of transfusion chain to ensure production of high-quality blood products to curtail transfusion related hazards.

CONCLUSION






The results of this study showed that the majority of whole blood derived red cell concentrates had a hematocrit level which was in conformity with the threshold setup by international guidelines.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

No.	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Muhammad Ali Rathore	Study conception and design, data collection, analysis and interpretation of results and manuscript preparation.	
2	Mommana Ali Rathore	Manuscript preparation, interpretation of results, data collection.	
3	Saadiya Mushtaq	Analysis and interpretation of results, manuscript preparation.	
4	Inaam Qadir Javed Hashmi	Study conception and design, analysis and interpretation of results, Critical review of final manuscript.	
5	Abdur Rehman Hashmi	Analysis and interpretation of results, manuscript preparation.	
6	Khadeeja Tul Kubra Hashmi	Manuscript preparation, interpretation of results.	