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Quality Assessment of Packed Red Cell Prepared by Different Methods

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Abstract

Background: Blood transfusion plays a pivotal role in modern health care systems. Since the advent of components preparation, Packed Red Cell (PRBC) prepared by any of the standard methods are maximum used components, followed by platelet concentrate (RDP) or single donor platelet (SDP). As per the Drug and Cosmetic Acts (1942), amended time to time, blood and its products are considered as a human product and therefore strict quality assurance should be followed as per standard operative procedure (SOP). The background of this study was to evaluate the quality assurance of PRBC prepared by the two methods in our center and to evaluate the best method to adopt.

Aim: to do the comparative study of quality assessment of PRBC prepared by two methods: buffy coat (BC) or platelet rich plasma (PRP) to evaluate the best method to adopt.

Methodology: As adopted in the present study was to assess the volume, hematocrit, potassium level, residual WBC, sterility, and hemolysis of the prepared bags by either method as per standard operative procedure (SOP).

Results: comprehensively the results obtained showed that as per volume and hematocrits, potassium level sterility and hemolysis there is no significance difference between two methods of preparation of PRBC, but residual WBC showed a statistically significant difference but in permissible limit as per SOP.

Conclusion: In conclusion it was discussed that most of the adverse transfusion reaction whether immediate or delayed are due to residuals WBC, lesser the WBC in PRBC, lesser the transfusion reaction, therefore as per result obtained PRBC prepared by BC methods will be better option.

Keywords: Whole Blood; PRBC; Quality Assessments; Residual WBC

Abbreviations

PRBC: Packed Red Blood Cell; RDP: Random Donor Platelets; SDP: Single Donor Platelet; PRP: Platelet Rich Plasma; BC: Buffy Coat; FDA: Food and Drug Administration; QA: Quality Assurance; QC: Quality Control; SAGM: Saline-Adenine-Glucose-Manitol; SOP: Standard Operating Procedure; TTI: Transfusion-Transmissible Infection. WBC: White Blood Cells; TMB: Tetra Methyl Benzoate; ANOVA: Analysis of variance; DGHS: Directorate General of Health Services; BC: Blood Collection; CPDA: Citrate-Phosphate-Dextrose Solution with Adenine; RBC: Red Blood Cells; HCL: Hydrochloric Acid; DNA: Deoxyribonucleic Acid; RNA: Ribonucleic acid; IQC: Internal Quality Control.

Introduction

Whole blood transfusion is a lifesaving process since 19th century when first man to man transfusion was recognized but it was not until the 20th century blood was used for less vital indication [1]. Whole blood remained to be standard of care for a long time due to many wars which led to the establishment of the first blood bank in 1916 to treat the severely bleeding soldiers by rapid transfusion [2]. Blood component therapy become the standard of transfusion medicine during the latter half of 20th century with the use of specialized equipment known as refrigerated centrifuge [3]. Component therapy is widely used as four components are generated out of one unit of whole blood, but it has been suggested in various studies that whole blood may be superior to packed red cell in case of trauma due to aim of volume replacement [4]. The principle behind preparation of component from blood involves each component having its own specific gravity and thus by applying centrifugation each component is separated and removed, thereby allowing the transfusion of desired components according to the need of the patients [5]. Another technique for preparation of components is filtration technique which is based on the size of components [6]. Two of the main methods used in component preparation using centrifugation technique are platelet Rich Plasma Techniques (PRP) and Buffy Coat (BC) method. Both the processes show several advantages and disadvantages not only in the method of preparation but also in the quality of yield of different components as well. The choice between the two methods is made by local supply, preference established during training or economic consideration [7].

The cornerstone of transfusion services all over the world relies on providing the right blood to the right person and at the right time [8,9]. The vital part of good transfusion practice includes the routine and timely quality analysis of various procedures to ensure the safety and adequacy of blood products. Quality analysis as a concept revolves around three basic principles- Quality control, quality assurance and quality management. Efficient and well-organized blood transfusion services apply the principles of quality analysis right from the process of collection from the donor to monitoring the adverse reactions in transfused recipients. It also includes routine and through quality check of reagents, Equipments and staff [10].

Quality assessment measures are important because of increased use of component therapy in clinical settings and because of the direct effect it has on the lives of the patients. Additionally, blood and blood components are grouped under drugs derived from human body. Hence the need for strict quality assurance measure as instructed by Drug controller of General of India [11].

The term hemovigilance was coined in France in 1991 derived from the Greek word's heme meaning blood and vigilance meaning watchful. The aim of hemovigilance is to detect and analyze the adverse effects of blood transfusion in order to correct their cause and to prevent their occurrence, thus improving the safety of blood transfusion. It is an important part of the quality system for blood transfusion and is defined as a set of surveillance methods covering the whole transfusion chain from the collection of blood and its separation into components to the follow-up of its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence [12].

Quality Assessment of Packed Red Blood Cells

Packed Red Cell (PRBC) is the key component most commonly used in clinical practice followed by platelet concentrate (random donor platelet or single donor platelet). The least used component is the cryoprecipitate. Therefore, transfusionist must concentrate more on quality assessment of PRBC. The parameters which should be analyse for strict quality control measurement should be volume of prepared PRBC per bags, hematocrits levels, potassium level, residual WBC, Hemolysis and Sterility of the prepared bags. The volume of prepared PRBC per bag mainly depends on the volume of blood collected during donation and type of primary bags whether top to top bags or top to bottom bags. It was noted that top to bottom bags gave better volume than top to top bags [13]. Hematocrit or hemoglobin level in the prepared blood bags of the PRBC by either method is important because in thalassemic patients or other anemia patients when it is required to build up the Hb for some operative procedures. It was emphasized that BC method is better in such situations [14,15]. Although there were some authors mentioned that handling and storage decline the hematological parameters such as hemolysis and therefore minimum handling should be performed and fresh blood should be given especially in pediatric patients, therefore regular quality assessments of the stored blood should be performed and inventory should be audited regularly in the centers where large quantity of blood are stored [16,17]. WBCs in whole blood or PRBCs cause many adverse transfusion reactions, including febrile non-hemolytic reactions, platelet transfusion refractoriness, graft-versus-host disease, and graft rejection [18]. To reduce these risks, leukoreduction became essential.

Fresh whole blood contains ~10^9 leukocytes, reduced to ~10^8 in PRBCs. AABB standards mandate leukocytes be under 5×106 per unit (3-log reduction) with 85% red cell recovery, while European guidelines require under 1×106 per units WBC [19,20]. The buffy coat method of preparation of PRBC already gave one log reduction and therefore superior

to the PRP method. At present, the best leukoreduction can be achieved with the help of 3rd and 4th generation leukofilters, both in laboratory and patient bed side [16]. Potassium Load of Blood Transfusions is well studied by various authors and emphasized that during storage, cells leak increasing amounts of their potassium content into the plasma and some cells lyse entirely. In the first few hours following a transfusion, some of the transfused cells fail to survive and their potassium is released into the patient's circulation. The remaining viable cells, however, take up potassium from the surrounding plasma, thus ultimately reverse some or all the extracellular load that has been administered. Fortunately, high potassium levels observed in stored blood may be of little concern in transfusion of single unit of red cells due to in vivo restoration of electrolyte balance in recipients' body [13,21,22]. Caution is advised, however, in cases of patients with cardiovascular disorders, pediatric patients and in patients with already established hyperkalemia [23,24]. Some authors highlighted the important of irradiation for increasing level of potassium in stored blood and emphasized that irradiation can improve the potassium level in the stored blood if it done in later period of storage rather than earlier days [25]. The marked variability in levels of potassium in stored PRBC units as well as rarity of any adverse events occurring post transfusion with units with a high potassium load may be the possible reasons why no clear guidelines have been established by any of the primary governing bodies of transfusion medicine [26]. It is well addressed that over the storage potassium level in the stored blood increases as sodium ions entered into the cell and potassium ions exit out from the cell, since the Na+/K+ pump is inactive at 4°C [27]. Although this is a totally reversible process as it took 24 hours to restore the physiological gradients for sodium, and up to 4 days for potassium [16,28-30]. The FDA established shelf-life is based on a minimum of 75% RBC survival in recipient circulation 24 h after transfusion [31].

Although at the temperature at which PRBC are store, it is difficult for any bacteria to grow, the sterility of the bag is more important for RDP or SDP due to storage at room temperature even then randomly selected PRBC bags should be send for bacterial culture as per guidelines [32,33].

Material & Methods

Study Design

Two-year prospective study design to study the comparison for QA of PRBC prepared by BC and PRP methods routinely used in our blood center.

QA Equipment's used

Thermo Scientific Heraeus Cryofuge 6000i for preparation of PRBC by either method. Terumo Penpol quadruple blood bags 450 ml with primary bag contain CPDA and one bag contain SAGM. Bags are immediately numbered and QR codes are issued. Samples were immediately taken for routine TTI and other parameters and preanalytical assessments of QC. Further bags are issued to component preparation lab for further processing as per SOP. Automatic component extractor by Terumo Penpol and Fresenius are used for extraction of components as per pre-installed programs in the machine.

410 bags were selected for evaluation in different periods of time for QC. Volume, Hematocrit, Potassium level, Residual WBC, Sterility and Hemolysis both qualitative and quantitative were estimated as per institutional guidelines. Volume is assessed by an electronic weighing machine (Terumo Penpol). The reference range for volume per bag as per SOP should be between 220–260 mL. Hematocrit was measured by hematology analyzer (Sysmax 3600). The Hct should be 55–60% as per guidelines adopted by our blood center. Potassium estimation was done by chemical method by ABG analyzer (Instrumentation Laboratory) and the recommended potassium levels was 2.5-5.5 mEq/L. Residual WBC also calculated by Hematology Analyzer. The result was obtained in µL and per bag WBC is calculated by multiplying the obtained value with volume of bag. The recommended Residual WBC per bag should be $<1x10^9$ per bag. Visual Hemolysis was seen by visually examining the segments by the naked eye. If any change of color was seen the quantitative estimation should be performed by Tetra Methyl Benzoate (TMB) method. No hemolysis should be seen qualitatively or quantitatively as per guidelines and institutional SOP. The sterility of the bags was examined by sending the bags for bacterial culture.

Statistical analysis was conducted by paired T test and Analysis of variance (ANOVA). Consent was taken by all the donors as per guidelines and institutional SOP. Ethical clearance was taken by Institutional Ethics Committee.

Results

The study conducted at JNMC AMU, Aligarh, examined 410 component bags prepared in the blood bank over a period of two years for routine quality assessment for PRBC prepared by different methods (PRP and BC methods). 210 units of packed red blood cells were prepared by the buffy coat (BC) method and 200 units prepared by the platelet-rich plasma (PRP) method. Routinely as per DGHS guideline and as per SOP of institutional Blood bank following parameters were assessed and presented in tabulated form in Table 1.

Volume

A total of 410 packed red blood cell components prepared by different methods were evaluated for volume.

The majority of PRBC prepared by both BC (90.95%) and PRP (95%) methods met the recommended volume criteria. The Volume in bags prepared by PRP methods showed mean ± SD of 262.87 ± 17.39 mL and by BC method as 260.53 ± 18.31. mL Statistical analysis (unpaired t-test) indicated a non-significant difference in mean volumes between PRBC prepared by BC and PRP methods, although it is noted that percentage of RBC loss is more in bags prepared by BC methods.

Hematocrit

Of the 320 bags assessed for hematocrit, 140 PRBC bags prepared by BC and 180 by PRP were evaluated. A significant majority of PRBC prepared by both BC (96.42%) and PRP (95%) methods showed hematocrit levels within the recommended range (50 – 60%), with statistical analysis (unpaired t-test) confirming a non-significant difference in mean hematocrit levels between the two preparation methods. The obtained values of Hct were 59.15±2.85% with PRP method whereas 58.37±2.69% were with BC methods.

Potassium

The study included a total of 186 bags of packed red blood cells (PRBC) for analysis potassium levels, with 94 bags prepared by the blood collection (BC) method and 92 by the platelet-rich plasma (PRP) method. The majority of PRBC units prepared by BC method had potassium levels between 11-13 mEq/L, while those prepared by PRP method showed levels between 7-9 mEq/L. Statistical analysis (unpaired t-test) revealed no significant difference in potassium levels between PRBC prepared by BC and PRP methods.

Additionally, potassium levels were monitored in PRBC units stored for different periods (10-20 days and 20-30 days). A significant difference in average potassium levels was observed between these storage periods (t-value = -7.55385, $p < .00001$), indicating higher potassium levels with longer storage (Table 2).

Residual WBC per unit

289 PRBC bags was assessed for white blood cell (WBC) counts, with 151 bags prepared by BC method and 140 by PRP method. The mean ±SD for residual WBC per bag prepared by PRP methods were 2.44±1.44 x106/ unit and 1.98±1.27x106/ unit prepared by BC methods. The study found a significant difference in WBC counts between PRBC prepared by BC and PRP methods. Although, majority of both groups had WBC contamination within permissible limits.

Hemolysis

Visual inspection for hemolysis in all evaluated units showed minimal incidence, with only one out of 410 bags demonstrating signs of hemolysis, that bag was prepared by PRP method.

Sterility

Sterility of the bags was assessed for microbiological culture indicated no contamination in any PRBC units prepared by either method.

	Methods	Total Bags Prepared	Mean ± SD	t test	Observation
Volume	PRP	210	262.87±17.39 mL	-1.32332	NS
	BC	200	260.53±18.31 mL		
Hct	PRP	180	59.15±2.85%	2.52115	Significance
	BC	140	58.37±2.69%		
Potassium Level	PRP	92	10.33±2.72 mEq/L	-1.62404	NS
	BC	94	10.33±2.72mEq/L		
Residual WBC	PRP	140	2.44± 1.44 x10^6/ unit	2.89973	Significance
	BC	151	1.98± 1.27x10^6/ unit		
Sterility	PRP	200	No Culture Positive		NS
	BC	210	No Culture Positive		
Hemolysis	PRP	200	No Hemolysis observed in 199 bags		Hemolysis in only 1 bag prepared by PRP
	BC	210	No Hemolysis observed		

PRP-Platelet Rich Plasma, BC-Buffy Coat Method, Ml-milliliter, mEq/L-Milliequivalent/liter, NS-non significant result.
Table 1: Observation Table.

Average of Potassium Levels in PRBC Units Between 10-20 days of Storage.	Average of Potassium Levels in PRBC Units Between 20-30 days of Storage	Paired t- Test	Observation
23.62±4.85mEq/L	41.642±5.47mEq/L	-7.55385	Significance

mEq/L-Milliequivalent/liter.

Table 2: Estimation of potassium in different days of storage.

Discussion

A unit of whole blood collected from a patient should be regarded as a precious asset with the potential of saving lives. Collection of whole blood from a donor and its transfusion as a whole is considered a thing of the past with the main aim of modern transfusion therapy being transfusion of only the required components. Each component is stored under ideal storage conditions with special preservative solutions and blood bags to lengthen the shelf life and improve quality of that component. The aim of PRBC transfusion as to maintain oxygen supply to the tissues when patient's red cells are lost as a result of bleeding or in cases of severe anemia when hemoglobin is dropped down to below 6 gm/dl with symptomatic patient and to build the patient for any major surgery. Further regular transfusion of PRBC is required by transfusion dependent thalassemic and other hemolytic anemia patients to maintain the Hb level above 9 gm/dl. Blood banks rely on good component separation practices to use the blood to its utmost potential [34]. With many varied aims, successful transfusion practices are based mainly on the premise of providing the right blood at the right time to the right patient [35]. Quality control of procedures, apart from temperature control at regular intervals is warranted to ensure adequacy and safety of the transfusion operations and is part of good transfusion practices [36].

Quality management in transfusion services includes all requisites of blood supply chain including donation of blood, appropriate blood collection practices, screening tests for transfusion transmitted infections, component preparation, product storage, transportation, and secure transfusion to the recipients [37].

Quality control is the central component of quality assurance programs in any transfusion service. It is the set of procedures undertaken for continuously and concurrently assessing blood bank work and the results in order to decide whether the performance is up to the mark and plays a vital role in blood transfusion safety. Risks allied with blood transfusion can be substantially reduced by the implementation of appropriate quality control [38].

PRBC is used in various medical and surgical situations with approximately 30% of critical care patients and more than 50% of cardiac surgery patients receiving blood products during their hospital stay. To ensure that PRBC are produced in a consistent and controlled manner, various blood collection agencies routinely test PRBC as part of their quality assurance programs and as part of their continuous improvement activities prior to making changes to equipment or processes [13,16,17,39].

Volume

It is an important parameter to be assessed during quality assurance and assessment, which depends on various factors. The amount of whole blood collected is the most important factor. The recommended volume of PRBC units prepared by either method ranges from 245 mL to 325 mL as per the National Accreditation Board for Hospitals and Healthcare Providers [13,39]. The PRBC prepared by the PRP and BC methods showed statistically non-significant results. In the study previously done by different authors showed variable results and depends upon the volume collected during donation. A comparative study was published in Transfusion showed that if collection was done in 500 ml bag the PRBC volume was in a range of 301±18mL to 328±17 mL whereas with a bag of 450 ml the mean volume was 263±25 mL and 296±16 mL by PRP and BC method respectively. There is a difference in volume of prepared volume of PRBC is top to top bag and top to bottom bags are used. In the present study we compared the volume by top-to-top bags only and well in accordance with previous studies [21-40].

Strict volume control is necessary because a higher volume of transfusion products leads to the complications such as circulatory overload, however they also emphasized on the importance of transfusing enough red cells to increase the hemoglobin concentration. Therefore, it is mandatory to transfuse PRBC which have a high red cell mass compared to their volume [3,15,41].

Hematocrit

To meet the requirement to transfuse more red cell mass compared to volume. Hematocrit is important.
Therefore, as per SOP the Hct of the PRBC after preparation should be between 60-70%, when stored in CPDA and 50-60%, when SAGM is added in the prepared PRBC bags. Hct of PRBC in the present study prepared by either method was well in accordance with the previous studies and within the permissible limit of guidelines follows in our center, although a high Hct up to 80% can also be achieved, but so much

concentrated blood can cause delay in transfusion through micro particle filters and restrict transfusion may cause post transfusion reaction. Although if high concentration is required, blood bank must be asked to make aliquot of small volume and transfusion should be done in part, and no transfusion should exceed 4 hours. In contrast to this some studies showed that preparation of PRBC by BC method led to approximately 20% loss of RBC during processing although there was higher platelet count in the platelet concentrates prepared from these units [37].

Even though regulatory standards vary with jurisdiction, it is recommended that the hematocrit of PRBC irrespective of the method of preparation of volume of donation should be less than 80% [36,39]. As per the National Accreditation Board for Hospitals and Healthcare Providers [40], the optimal hematocrit of PRBC units prepared from 350 ml whole blood is 55-65%. In the present study the majority of PRBC prepared by BC method and PRP method showed hematocrit within the recommended range of previous studies, regulatory body guidelines and as per SOP of our blood bank [17].

Potassium level

Potassium Load of Blood Transfusions is well studied by various authors and emphasized that during storage, cells leak increasing amounts of their potassium content into the plasma and some cells lyse entirely. In the first few hours following a transfusion, some of the transfused cells fail to survive and their potassium is released into the patient's circulation. The remaining viable cells, however, take up potassium from the surrounding plasma, thus ultimately reverse some or all the extracellular load that has been administered. Fortunately, high potassium levels observed in stored blood may be of little concern in transfusion of single unit of red cells due to in vivo restoration of electrolyte balance in recipients' body [40,42]. Caution is advised, however, in cases of patients with cardiovascular disorders, pediatric patients and in patients with already established hyperkalemia [23,25]. It was advised that if stored blood is to be transfused irradiation can improve the outcome in these patients in another study. They emphasized that irradiation in later period of storage gave better result that earlier day [25].

The marked variability in levels of potassium in stored PRBC units as well as rarity of any adverse events occurring post transfusion with units with a high potassium load may be the possible reasons why no clear guidelines have been established by any of the primary governing bodies of transfusion medicine [24,25,27]. The potassium level estimated in our study in PRBC prepared by different methods showed and compatible with studies did in the past.

It is well addressed that over the storage potassium level in the stored blood increases as sodium ions entered into the cell and potassium ions exit out from the cell, since the Na^+/K^+ pump is inactive at 4°C [27], Although this is a totally reversible process as it took 24 hours to restore the physiological gradients for sodium, and up to 4 days for potassium [29,27]. Over the course of storage, 10 bags each irrespective of the method of preparation were analyzed for potassium levels and divided into 2 batches depending on the period of storage. The rise in serum potassium over the course of storage was statistically significant. These results were well compatible with previously conducted studies [19,29-31].

Residual WBC

WBC in whole blood or PRBC is the main culprit for most of Adverse transfusion reaction such as febrile non-hemolytic transfusion reactions, refractoriness to platelet transfusion, graft-versus-host disease, generalized immunosuppression, and an increased graft rejection rate of marrow or kidney transplantations [13,17]. Consequently, the need to reduce the residual white blood cell arises and component therapy came into practice. It has been estimated that a freshly collected, whole blood unit contains roughly 10^9 leukocytes, and their concentration is around 10^8 in PRBC, this is denoted as 1 log reduction [38]. According to the American Association of Blood Banks standards, leukocyte numbers in a blood component should be reduced to less than 5×10^6 per unit after leukoreduction (achieving a 3 log reduction, or 99.9% reduction), with at least 85% recovery of red cells in 95% of units tested. In contrast, the European council guidelines are stricter, requiring residual leukocyte content to be less than 1×106 per unit [17,19,20]. The buffy coat method of preparation of PRBC already gave one log reduction and therefore superior to the PRP method. At present, the best leukoreduction can be achieved with the help of 3rd and 4th generation leukofilters, both in laboratory and patient bed side. The present study showed a significant reduction of residual WBC in PRBC prepared by different method and PRBC prepared by BC method show better reduction as compared to PRP method [43].

Visual Haemolysis

All units prepared using both methods were assessed for haemolysis during the course of present study. None of the evaluated units exhibited any obvious visual signs of haemolysis. Haemolysis is an indicator of the overall structural integrity of red blood cells (RBCs), which can increase due to physical handling, temperature fluctuations,

prolonged storage, and changes in the extracellular storage solution. Notably, the study found that haemolysis was least in PRBC units collected from menstruating females, attributing this to the higher number of younger RBCs in their circulation [3,28].

The degree of haemolysis is measured as the percentage of free hemoglobin relative to total hemoglobin, adjusted for hematocrits. According to research, despite the use of additive solutions and leukoreduction filters, some haemolysis is unavoidable. However, the extent of haemolysis in a PRBC unit should not exceed the permissible threshold even after 42 days of storage [17,44].

Visual examination for haemolysis, particularly in the attached segments, revealed no significant signs. The recommended maximum levels of haemolysis are 1% as per AABB guidelines and 0.8% in European guidelines. It is standard practice in our blood bank to check for haemolysis before issuing PRBC units, and any unit showing obvious signs of haemolysis is not used for transfusion. The extremely low haemolysis at our center is likely due to the use of SAGM additive, where mannitol stabilizes the membrane and acts as a free radical scavenger. Additionally, the use of DEHP as a plasticizer in blood bags contributes to membrane stabilization [14,29,45]. While visual detection of haemolysis is quick, it often overestimates the extent of haemolysis. Newer methods, such as the TMB method, can provide more accurate assessments [29].

Sterility

All units examined for quality control were tested for bacterial contamination through culture methods. None of the units showed any signs of contamination. Since the 1980s, following the discovery of human immunodeficiency virus contamination in the blood supply, ensuring a zero-risk blood supply has become a political necessity [46]. Barrett BB, et al. [47] found that only 0.03% of the 31,385 PRBC units in their blood bank were contaminated by bacteria, using gram staining and bacterial culture methods. The even lower contamination rate in our study can be attributed to the smaller number of units examined [47]. Recent studies also showed that although PRBC bags are stored at 4°C, the growth of bacteria is not possible but concern for sterility should be more important for RDP and SDP as they stored at room temperature [32,33]. Several strategies exist to reduce transfusion-related bacterial infection, categorized into four major approaches:

Avoidance, which includes donor screening and proper skin preparation before drawing blood [48]. Use of diversion pouch to collect few ml of blood before collection of blood in primary bag after venipuncture [49]. Bacterial detection using methods such as bacterial culture, gram staining, and advanced detection systems [50].

Bacterial elimination through advanced methods like amotosalen HCL (S-59), a synthetic psoralen combined with photochemical treatment to create permanent DNA and RNA cross-links, destroying organisms [51]. Growth inhibition by adding antibiotics to the blood [52].

Conclusion

In conclusion, the quality assessment of Packed Red Blood Cells (PRBC) is essential for ensuring the safety, efficacy, and optimal therapeutic outcomes in transfusion medicine. This study, conducted on 410 PRBC bags prepared using different methods, highlights the critical role of quality assessment in distinguishing the superiority of various preparation techniques. Among the methods evaluated, Buffy Coat (BC) preparation was identified as superior, particularly in terms of yielding a higher quality of RDP. The volume, Hct, Residual WBC and hemolysis are important parameters were evaluated for quality check and found to be at par with the institutional guidelines. The findings highlighted the importance of rigorous quality control measures in blood component preparation, which are vital for maximizing the clinical benefits of PRBC transfusions and improving patient care.

Internal Quality Control (IQC) is a crucial element of quality assurance in laboratory services. It involves pre-defined procedures for the continuous assessment of routine work to evaluate performance standards. In blood banks, maintaining these quality control standards helps to reduce the incidence of adverse blood reactions. Regular periodic quality analysis of blood components is essential to monitor variations in manufacturing processes and product quality, ensuring that each step in the manufacturing process meets the established acceptance criteria as per guidelines adopted in the blood bank.

Conflict of Interest

No conflict of interest

Funding

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Ethical Clearance

Ethical clearance is taken from Institutional Ethics Committee

References

1. Schmidt PJ, Leacock AG (2002) Forgotten transfusion history: John Leacock of Barbados. BMJ 325(7378): 1485-1487.

2. Spinella PC, Perkins JG, Grathwohl KW, Beekley AC, Holcomb JB (2009) Warm fresh whole blood is independently associated with improved survival for patients with combat-related traumatic injuries. Journal of Trauma and Acute Care Surgery 66(4): S69-S76.

3. Acker JP, Marks DC, Sheffield WP (2016) Quality assessment of established and emerging blood components for transfusion. Journal of blood transfusion 2016(1): 4860284.

4. Zielinski MD, Jenkins DH, Hughes JD, Badjie KS, Stubbs JR (2014) Back to the future: The renaissance of whole-blood transfusions for massively hemorrhaging patients. Surgery 155(5): 883-886.

5. Moog R (2006) A new technology in blood collection: Multicomponent apheresis. In: Peterson BR (Ed.), New Developments in Blood Transfusion Research, USA, Inc, pp: 141-146

6. Basu D, Kulkarni R (2014) Overview of blood components and their preparation. Indian Journal of Anesthesia 58(5): 529-537.

7. Vassallo RR, Murphy S (2006) A critical comparison of platelet preparation methods. Curr Opin Hematol 13(5): 323-330.

8. Letowska M (2009) Patient-specific component requirements: 'right blood, right patient, right time, right place.' ISBT Science Series 4(1): 52-55.

9. Shaffer L (2020) Making and storing blood to save lives. Proceedings of the National Academy of Sciences 117(14): 7542-7545.

10. World Health Organization (2004) External quality assessment of transfusion laboratory practice: guidelines on establishing an EQA scheme in blood group serology. Geneva WHO PP: 72.

11. Saran RK (2003) Transfusion Medicine Technical Manual, 2nd (Edn.), Mehta Offset, India, pp: 395.

12. De Vries RR, Faber JC, Strengers PF (2011) Board of the International Haemovigilance Network. Haemovigilance: an effective tool for improving transfusion practice. Vox Sanguinis 100(1): 60-67.

13. Murphy S (2005) Platelets from pooled buffy coats: an update. Transfusion 45(4): 634-639.

14. Jain R, Sachdev S, Marwaha N, Gupta A (2022) Assessment of Hemoglobin Content of Packed Red Cells: A prospective Study on Hemoglobin Content Variation Due to Donor, Collection, and Processing-Related Factors. Is it Time to Label Each Unit with Hemoglobin Content? Global Journal of Transfusion Medicine 7(1): 36-41.

15. Schiroli D, Merolle L, Quartieri E, Chicchi R, Fasano T, et al. (2021)Comparison of two alternative procedures to obtain packed red blood cells for β-thalassemia major transfusion therapy. Biomolecules 11(11): 1638.

16. Stone M, Keating SM, Kanias T, Lanteri MC, Lebedeva M, et al. (2019) Piloting and implementation of quality assessment and quality control procedures in RBC-Omics: a large multi-center study of red blood cell hemolysis during storage. Transfusion 59(1): 57-66.

17. Gupta AN, Bala GU, Suri VI, Dhingra HA, Chhabra SA, et al. (2019) Quality Analysis of Hematological Parameters of Whole Blood, Packed Red Blood Cells and Platelet Concentrate: A Study from Tertiary Care Hospital of Northern India. J Clin Diagn Res 13(11): 1-4.

18. Chu RW (1999) Leukocytes in blood transfusion: adverse effects and their prevention. Hong Kong Med J. 5(3): 280-284.

19. Sharma RR, Marwaha N (2010) Leukoreduced blood components: Advantages and strategies for its implementation in developing countries. Asian J Transfus Sci 4(1): 3-8.

20. AABB (1999) Collection, Preparation, Storage, and Distribution of Components. In: Tayler VV (Ed.), AABB Technical manual, 13th (Edn.), USA, pp: 175-176.

21. Olson J, Talekar M, Sachdev M, Castellani W, De la Cruz N, et al. (2013) Potassium changes associated with blood transfusion in pediatric patients. Am J Clin Pathol 139(6): 800-805.

22. Campbell-Lee SA (2003) Packed RBCs and related products. Blood Banking and Transfusion Medicine. In: Basic Principles and Practice, Ness P, Silberstein LE, Anderson KC, Roback JD (Eds.), 2nd (Edn.), Philadelphia, PA: Churchill Livingstone pp: 145-152.

23. Klein HG, Spahn DR, Carson JL (2007) Red blood cell transfusion in clinical practice. Lancet 370(9585): 415-426.

24. Rizos CV, Milionis HJ, Elisaf MS (2017) Severe hyperkalemia following blood transfusions: Is there a link? World J Nephrol 6(1): 53-56.

25. Balasubramanyam P, Basavarajegowda A, Hanumanthappa N, Negi VS, Harichandrakumar KT (2021) Irradiating stored blood and storing irradiated blood: Is it different?-A study of serial changes in biochemical parameters of red blood cell units. Asian Journal of Transfusion Science. Asian J Transfus Sci 15(2): 172-178.

26. Bennett-Guerrero E, Veldman TH, Doctor A, Telen MJ, Ortel TL, et al. (2007) Evolution of adverse changes in stored RBCs. Proc Natl Acad Sci 104(43): 17063-17068.

27. Hogman CF, Meryman HT (1999) Storage parameters affecting red blood cell survival and function after transfusion. Transfus Med Rev 13(4): 275-296.

28. Sawant RB, Jathar SK, Rajadhyaksha SB, Kadam PT (2007) Red cell hemolysis during processing and storage. Asian J Transfus Sci 1(2): 47-51.

29. Arif SH, Yadav N, Rehman S, Mehdi G (2017) Study of hemolysis during storage of blood in the blood bank of a tertiary health care centre. Indian J Hematol Blood Transfus 33(4): 598-602.

30. Mukherjee S, Marwaha N, Prasad R, Sharma RR, Thakral B (2010) Serial assessment of biochemical parameters of red cell preparations to evaluate safety for neonatal transfusions. Indian J Med Res 132(6): 715-720.

31. Pulliam KE, Joseph B, Veile RA, Friend LA, Makley AT, et al. (2021) Expired but not yet dead: examining the red blood cell storage lesion in extended-storage whole blood. Shock 55(4): 526-535.

32. Gojkov D, Borovcanin N, Vucetic D (2023) Sterility testing of platelets concentrate within quality control: experiences and opportunities to extend the application. Experimental and Applied Biomedical Research (EABR) 24(1): 27-32.

33. Khodair SA, El-Shalakany AH, Shalaby SM (2020) Bacterial Contamination of Stored Blood and Blood Components Ready for Transfusion at the Blood Bank. Egyptian Journal of Medical Microbiology 29(3): 53-7.

34. Hardwick J (2008) Blood processing. ISBT Science Series 3(2): 148-176.

35. Upadhyay S, Pangtey T (2016) Quality Analysis of Blood Component (PRBC and Platelet Concentrates): A Study from A Tertiary Care Teaching Hospital of Kumaon Region of Uttarakhand. J Evol Med Dent Sci. 5(23): 1210-1212.

36. Sultan S, Zaheer HA, Waheed U, Baig MA, Rehan A, et al. (2018) Internal quality control of blood products: An experience from a tertiary care hospital blood bank from Southern Pakistan. J Lab Physicians 10(1): 64-67.

37. Ferreira ÂM, Brener S, Carvalho RV, Valle MC, Moraes-Souza H (2012) Participation in proficiency programs and promotion of quality in transfusion services of Minas Gerais. Rev Bras Hematol Hemoter 34(1): 21-24.

38. Raghavan M, Marik PE (2005) Anemia, allogenic blood transfusion, and immunomodulation in the critically ill. Chest 127(1): 295-307.

39. Van Delden CJ, De Wit HJ, Sibinga CT (1998) Comparison of blood component preparation systems based on buffy coat removal: component specifications, efficiency, and process costs. Transfusion 38(9): 860-866.

40. National Accreditation Board for Hospitals & Healthcare Providers (2020) Hospital Accreditation Program: Policy & Guidelines for Use of NABH Accreditation Certification. Nabh.

41. Oh JY, Marques MB, Xu X, Li J, Genschmer K, et al. (2020) Damage to red blood cells during whole blood storage. J Trauma Acute Care Surg 89(2): 344-350.

42. Malament IB, Uhlman W, Eisinger RP (1975) Potassium Load of Blood Transfusions. Int Urol Nephrol 7(3): 215-217.

43. Garcia-Roa M, Del Carmen Vicente-Ayuso M, Bobes AM, Pedraza AC, González-Fernández A, et al. (2017) Red blood cell storage time and transfusion: current practice, concerns and future perspectives. Blood Transfus 15(3): 222-231.

44. Makroo RN, Raina V, Bhatia A, Gupta R, Majid A, et al. (2011) Evaluation of the red cell hemolysis in packed red cells during processing and storage. Asian J Transfus Sci 5(1): 15-17.

45. Sowemimo-Coker SO (2002) Red blood cell hemolysis during processing. TransfusMed Rev. Transfus Med Rev 16(1): 46-60.

46. Zuck TF (1987) Greetings-a final look back with comments about a policy of a zero-risk blood supply. Transfusion 27(6): 447-448.

47. Barrett BB, Andersen JW, Anderson KC (1993) Strategies for the avoidance of bacterial contamination of blood components. Transfusion 33(3): 228-233.

48. McDonald CP, Lowe P, Roy A, Robbins S, Hartley S, et al. (2001) Evaluation of donor arm disinfection techniques. Vox Sang 80(3): 135-141.

49. Lee CK, Wong HK, Ho PL, Tsoi WC, Lee KY, et al. (2012) Significant bacterial contamination risk reduction with the use of diversion pouch. Transfus Med 22(6): 404-408.

50. Brecher ME, Means N, Jere CS, Heath D, Rothenberg S, et al. (2001) Evaluation of an automated culture systemfor detecting bacterial contamination of platelets: an analysis with 15 contaminating organisms. Transfusion 41(4): 477-482.

51. Wollowitz S (2001) Fundamentals of the psoralen-based Helinx technology for inactivation of infectious pathogens and leukocytes in platelets and plasma. Semin Hematol 38(4 Suppl 11): 4-11.

52. Jackson BR, Busch MP, Stramer SL, AuBuchon JP (2003) The cost-effectiveness of NAT for HIV, HCV, and HBV in whole-blood donations. Transfusion 43(6): 721-729.