Original Article

Quality Control of Red Cell Concentrates: An Insight into the Effective Functioning of the Blood Centre

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Abstract

Background: The global adoption of blood component therapy has led to the establishment of quality control programs in blood centers, ensuring the safety and efficacy of blood components. Quality control guarantees the availability of high-quality blood components, minimizing the risk of transfusion-related adverse events. As red cell concentrates are used daily in our blood center, evaluating their quality control processes is crucial. This study aimed to assess the quality control processes for red cell concentrates at our blood center.

Materials and Methods: A 5-year retrospective study was conducted at a blood center attached to a tertiary care hospital. Data was collected from 2019 to 2023. A total of 48,662 units of blood were collected during this period. Whole blood was subjected to component separation, and 46,930 units of red cell concentrates were prepared. Four units per month, or 1% of red cell concentrates prepared, were subjected to quality control as per the standard guidelines.

Results: The mean volume of red cell concentrates prepared from 350 ml and 450 ml whole blood without additive solution was 158.98 ml and 243.13 ml, respectively, whereas those prepared with additive solution were 241.79 ml and 314.46 ml, respectively. A total of 81.12% of red cell concentrates without additive solution met the quality standard (hematocrit 65–70%). Additionally, 86.69% of red cell concentrates with additive solution met the quality standard (hematocrit 50–60%).

Conclusion: Our study confirms that the quality of red cell concentrates meets standard guidelines. Routine quality control is essential to ensure efficacy, minimize transfusion risks, and drive manufacturing advancements.

Keywords:

Hematocrit, volume, quality control, red cell concentrates

Introduction

Blood transfusion services are a vital component of healthcare, providing life-saving interventions in emergency situations and supporting the treatment of various medical conditions, making them an essential part of comprehensive patient care [1]. The risks associated with blood transfusions, stemming from technical and human errors, underscore the critical need for rigorous quality control measures to guarantee the delivery of safe, effective, and reliable blood products, thereby protecting patient safety and trust [2].

Important considerations to ensure the availability of safe blood and its components include the recruitment of voluntary, non-remunerated blood donors; standardized screening and testing; assessment and selection of healthy blood donors; appropriate and adequate blood collection; and the retention of these safe donors.

Internal quality control is the pillar of the quality evaluation system in the blood centre. Integrating hemovigilance with continuous quality surveillance is essential for blood centres to provide optimal transfusion services, guaranteeing the safety, efficacy, and excellence of blood products for patients in need. Quality control measures are implemented to detect deviations in manufacturing processes and product quality, ensuring that production steps conform to established standards [3].

Modern blood banking prioritizes quality control to provide high-quality blood components with optimal efficacy and safety for recipients. This ensures that blood products are available promptly and meet the highest standards, making a significant difference in patient care and outcomes [4].

Given the frequent use of red cell concentrates at our blood centre, a comprehensive quality control program is vital to maintain the highest standards of product quality. This encompasses rigorous testing protocols, strict handling and storage procedures, and continuous monitoring to guarantee efficacy and compliance with regulatory requirements, ultimately protecting patient safety and care.

The aim of this study was to evaluate the quality control processes for red cell concentrates at our blood centre, examining their impact on product safety, efficacy, and the overall efficiency of our blood centre operations.

Materials and Methods

The current study was a retrospective study conducted at the blood centre attached to a tertiary care hospital, following approval from the Institutional Ethics Committee and after obtaining necessary permissions from the records in charge of the blood centre.

Quality control testing is regularly performed at our blood centre in accordance with the protocols outlined in the Technical Manual of Transfusion Medicine by the Directorate General of Health Services, Ministry of Health and Family Welfare, India [2]. Data was collected retrospectively from blood centre records between January 1, 2019, and December 31, 2023. A total of 48,662 units of blood were collected during this period from screened, healthy donors weighing more than 50 kg.

To ensure the safety of both donors and recipients, strict eligibility criteria were applied for blood donation. Donors had to be between 18 and 65 years of age, in good physical and mental health, and meet a minimum interval of three months since their last donation. A hemoglobin level greater than 12.5 g/dL was required for eligibility. Donors were screened for transmissible diseases and had to present normal vital signs, including blood pressure, pulse, and temperature. These stringent criteria ensured the safety and quality of the blood supply. Blood was collected from voluntary donors after obtaining written informed consent, either at the in-house blood collection centre or during blood donation camps organized by NGOs, religious organizations, and community groups.

Sterile single, double, or triple blood bags (HLL Donato, Terumo Penpol, Polymed) with a volume of 350/450 ml and containing the anticoagulant CPDA-1 (citrate phosphate dextrose adenine 1) were used for collection. Whole blood donations from donors weighing over 60 kg, collected in double or triple bags, were processed for component separation using the refrigerated centrifuge Heraeus Cryofuge 6000i by Thermo Fisher Scientific.

Blood collected in CPDA-1 bags with attached satellite bags (double and triple) was properly labeled with the bag number,

collection date, and expiry date. After collection, the blood was kept at room temperature before being transferred to the component preparation room and processed within six hours. Bags were placed in buckets, balanced by weight, and centrifuged. In the case of double bags, high-spin centrifugation at 3,000 rpm at 4°C for 12 minutes was performed. For triple bags, low-spin centrifugation at 1,500 rpm at 22°C for 15 minutes was used.

Following centrifugation, bags were removed and placed on the expresser stand under laminar flow. The seal of the primary bag's connecting tube was broken, and plasma was expressed manually into the satellite bag, leaving 50–60 ml of plasma with red cells in the primary bag, labelled as red cell concentrate.

When additive solution (SAGM – Saline, Adenine, Glucose, Mannitol) bags were used, SAGM was transferred from the plasma bag to an empty pouch. After plasma separation, the solution was slowly mixed into the primary bag. The tubing was sealed, and the bags were detached. The packed red blood cell bags were weighed and stored at 2°C to 6°C. SAGM bags had a shelf life of 42 days, while CPDA bags were used within 35 days. Platelet-rich plasma (from triple bags) was centrifuged at 3,000 rpm for 9 minutes at 22°C to separate platelets.

Quality control procedures involved testing a minimum of four units or 1% of the total monthly red cell concentrates, following guidelines from the Technical Manual of Transfusion Medicine [2]. During the study period, 46,930 units of red cell concentrates were separated from the 48,662 units collected. Of these, 474 units (1.01%) were randomly selected for monthly internal quality control testing. All products were evaluated at the end of each month.

The volume of blood bags was calculated using the following formula: Volume (ml) = (Weight of bag + blood (g) – Weight of empty bag (g)) / 1.053 Standard calibrated weighing scales were used for measurements. Hematocrit levels were determined using the automated 5-part differential Nihon Kohden Celltac Es MEK-7300 hematology analyzer.

Statistical Analysis: SPSS (version 22.0, IBM, 2020, Armonk, New York, USA) was used to analyze the data. Volume and hematocrit levels were statistically assessed using measures of central tendency (mean) and variability (range and standard deviation) to summarize the findings.

Results

A total of 48,662 units of blood were collected during the study period from January 2019 to December 2023. Out of these, 47,009 units (96.6%) were processed for component separation. A total of 94,129 components, including red cell concentrates, fresh frozen plasma (FFP), platelet concentrate, and cryoprecipitate, were prepared. Among these, 46,930 units of red cell concentrates were separated (Figure 1). The study performed quality control of red cell concentrates prepared from 350 ml and 450 ml of whole blood collected at our blood centre.

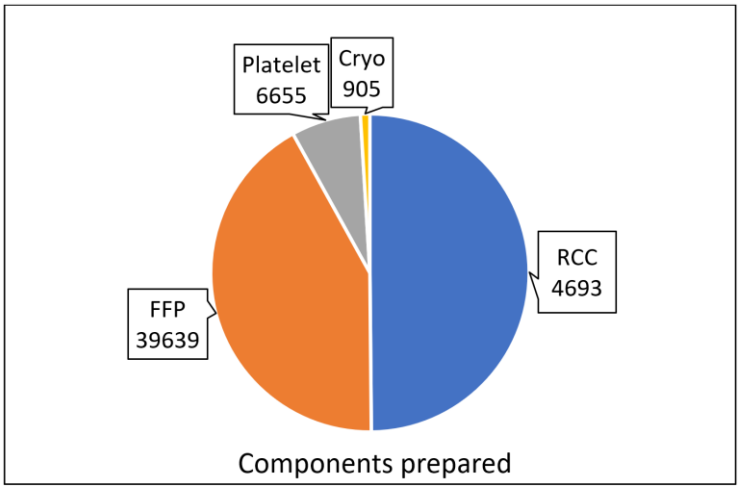

Figure 1: Components Prepared

Out of the 46,930 units of red cell concentrates prepared, 1.01% (474 units) were randomly tested for quality analysis parameters, specifically total volume and haematocrit. This was conducted in accordance with the established guidelines and standard operating procedures of our blood centre. The 474 units comprised 196 red cell concentrates prepared without additive solution and 278 prepared with additive solution (SAGM), separated from 350 ml and 450 ml blood bags.

Table 1: Quality Control of Red Cell Concentrates Prepared from 350 ml Whole Blood Without Additive Solution (n=113)

Parameter	Mean ± SD	Range	Acceptable Range	Concordance
Volume (ml)	158.98 ± 12.15 ml	130-200 ml	135-165 ml	95/113 (84.07%)
Haematocrit (%)	66.99 ± 2.98%	59-73.84%	65-70%	93/113 (82.30%)

Table 2: Quality Control of Red Cell Concentrates Prepared from 450 ml Whole Blood Without Additive Solution (n=83)

Parameter	Mean ± SD	Range	Acceptable Range	Concordance
Volume (ml)	243.13 ± 14.20 ml	220-270 ml	225-275 ml	70/83 (84.33%)
Haematocrit (%)	66.95 ± 2.97%	58.7-74.2%	65-70%	66/83 (79.51%)

The mean volume of red cell concentrates prepared from 350 ml whole blood was 158.98 ml, with a range of 130-200 ml. Mean haematocrit levels were 66.99%, with a range of 59-73.84%. For 450 ml whole blood, the mean volume was 243.13 ml (range: 220-270 ml) and haematocrit levels averaged 66.95%, with a range of 58.7-74.2%.

According to standard guidelines, red cell concentrates prepared from 350 ml and 450 ml whole blood without additive solution should have haematocrit levels between 65-70%. At our blood centre, 81.12% (159/196) of the tested red cell concentrates met the quality requirements for haematocrit [2].

Table 3: Quality Control of Red Cell Concentrates Prepared from 350 ml Whole Blood With Additive Solution (n=156)

Parameter	Mean ± SD	Range	Acceptable Range	Concordance
Volume (ml)	241.79 ± 13.03 ml	200-275 ml	225-275 ml	147/156 (94.23%)
Haematocrit (%)	56.12 ± 3.92%	47.3-66.4%	50-60%	139/156 (89.10%)

Table 4: Quality Control of Red Cell Concentrates Prepared from 450 ml Whole Blood With Additive Solution (n=122)

Parameter	Mean ± SD	Range	Acceptable Range	Concordance
Volume (ml)	314.46 ± 24.77 ml	240-350 ml	315-385 ml	95/122 (77.86%)
Haematocrit (%)	56.47 ± 4.12%	48.5-67.4%	50-60%	102/122 (83.60%)

The mean volume of red cell concentrates prepared from 350 ml whole blood with additive solution (SAGM) was 241.79 ml (range: 200-275 ml), with mean haematocrit levels of 56.12% (range: 47.3-66.4%). For 450 ml whole blood, the mean volume was 314.46 ml (range: 240-350 ml) and mean haematocrit levels were 56.47% (range: 48.5-67.4%).

Standard guidelines stipulate that red cell concentrates prepared from 350 ml and 450 ml whole blood with additive solution should have haematocrit levels between 50-60%. At our blood centre, 86.69% (241/278) of the tested red cell concentrates met this requirement [2].

All red cell concentrates subjected to quality control testing were non-reactive for Hepatitis B virus, HIV 1 & 2, Hepatitis C virus, Malaria, and Syphilis.

Discussion

Red cell concentrates are a component of blood prepared by separating plasma from centrifuged whole blood. Red cell concentrate transfusions increase the volume of circulating red cells in conditions where tissue oxygenation may be impaired by acute or chronic blood loss, such as in haemorrhage or anaemia. Transfusing 1 unit of red cell concentrate increases haemoglobin by about 1 g/dL and haematocrit by approximately 3% in an average 70-kg adult [5].

Internal quality control plays a vital role in the efficient and safe preparation of blood and its components. The cornerstone of all laboratory services, including blood banks, is quality control. Safer and more effective blood components for transfusion have been developed through rigorous quality control testing. Regular analysis of blood components is essential to verify the effectiveness of transfusions in clinical settings. Quality control methods ensure the viability and efficacy of blood products, leading to safer transfusions. Internal quality control, in turn, ensures the efficacy of blood bank operations and outcomes, reducing transfusion-associated risks and fostering advancements in manufacturing methods [4].

Red cell concentrates are widely used, making regular quality evaluation of haematological parameters crucial to ensure optimal performance, safety, and quality. Two key internal quality control parameters — volume and haematocrit level — are essential for assessing the quality of red cell concentrates, in accordance with established guidelines. This study aimed to investigate the quality specifications of red cell concentrates derived from whole blood.

Our study assessed the volume and haematocrit levels in stored red cell concentrate units at the end of each month. Of 46,930 units prepared over five years, 474 (1.01%) were arbitrarily selected for quality analysis of parameters such as total volume and haematocrit. All tested parameters aligned with standard guidelines.

According to reference standards, the volume of red cell concentrates prepared without an additive solution (SAGM) should be 250 ± 10% for a 450 mL blood bag and 150 ± 10% for a 350 mL blood bag. The haematocrit should be 65-70%. For red cell concentrates prepared with an additive solution (SAGM), the volume should be 350 ± 10% for a 450 mL blood bag and 250 ± 10% for a 350 mL blood bag, with haematocrit levels of 50-60%. At least 75% of tested units must meet these quality standards

[2].

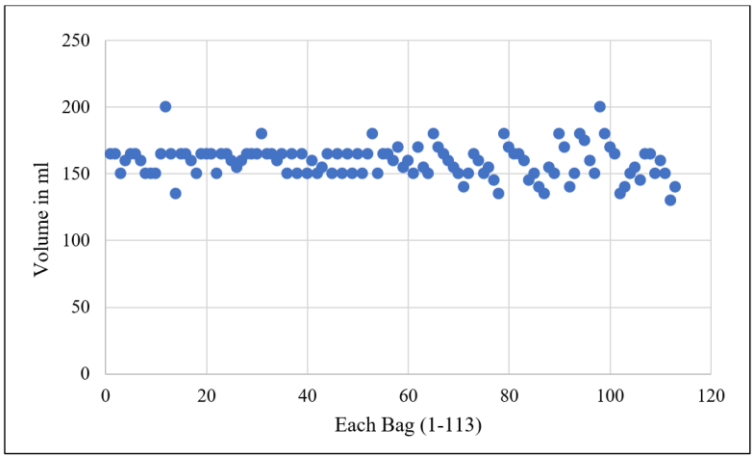

Figure 2: Volume of red cell concentrates from 350 mL whole blood without additive solution (n = 113).

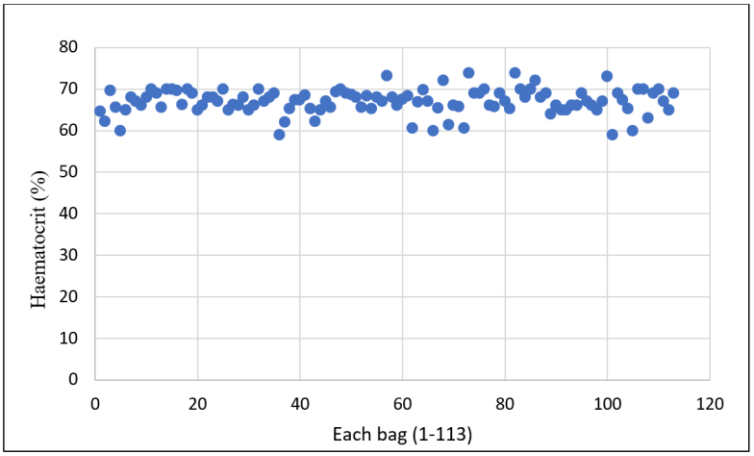

Figure 3: Haematocrit levels of red cell concentrates from 350 mL whole blood without additive solution (n = 113).

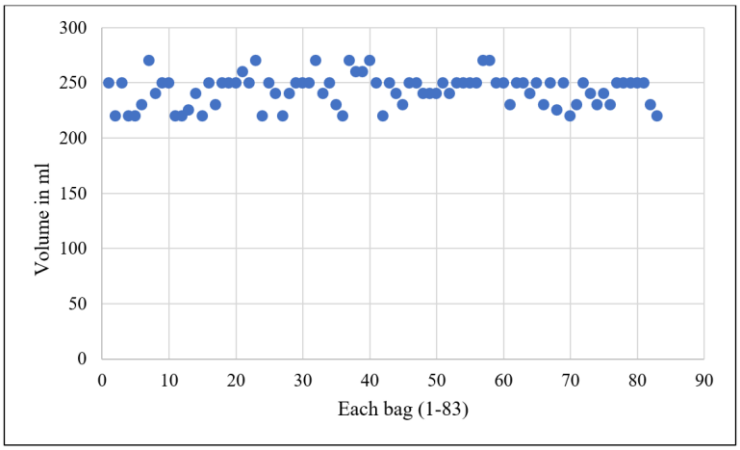

Figure 4: Volume of red cell concentrates from 450 mL whole blood without additive solution (n = 83).

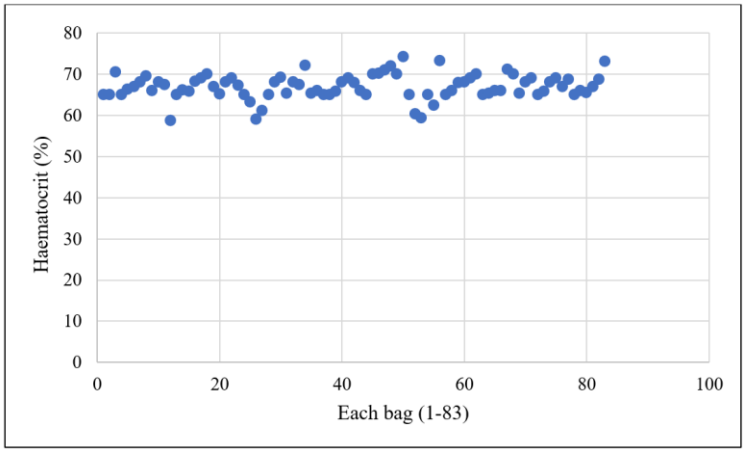

Figure 5: Haematocrit levels of red cell concentrates from 450 mL whole blood without additive solution (n = 83).

In our study, the mean ± SD volume of red cell concentrates prepared from 350 mL and 450 mL whole blood without additive solution (196 units) was 158.98 ± 12.15 mL and 243.13 ± 14.20 mL, respectively. The mean ± SD haematocrit levels were 66.99 ± 2.98% for red cell concentrates from 350 mL whole blood and 66.95 ± 2.97% for those from 450 mL whole blood. A total of 81.12% (159/196) of these units met the quality requirement of haematocrit levels between 65-70%, as per reference guidelines (Figures 2, 3, 4, and 5).

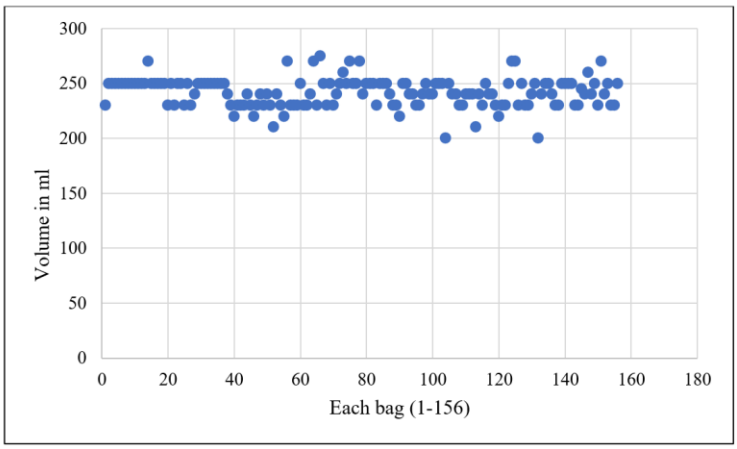

Figure 6: Volume of red cell concentrates from 350 mL whole blood with additive solution (n = 156).

The mean ± SD volume of red cell concentrates prepared from 350 mL and 450 mL whole blood with additive solution (278 units) was 241.79 ± 13.03 mL and 314.46 ± 24.77 mL, respectively. The mean ± SD haematocrit levels were 56.12 ± 3.92% for concentrates from 350 mL whole blood and 56.47 ± 4.12% for those from 450 mL whole blood. A total of 86.69% (241/278) of these units met the quality requirement of haematocrit levels between 50-60% (Figures 6, 7, 8, and 9).

Overall, >75% of red cell concentrates prepared from 350 mL or 450 mL whole blood, with or without additive solution, met quality standards in our study. This indicates that our blood centre follows appropriate procedures to ensure the quality of red cell concentrates.

Our findings align with a 2022 study by Das et al. in India, which assessed red cell concentrate quality based on the Drugs and

Cosmetics Act, AABB standards, the European Committee on Blood Transfusion guidelines, and NABH standards. Their study reported a mean ± SD volume of 200.55 ± 17.88 mL and haematocrit of 56.63 ± 5.89% for red cell concentrates from 350 mL whole blood [3].

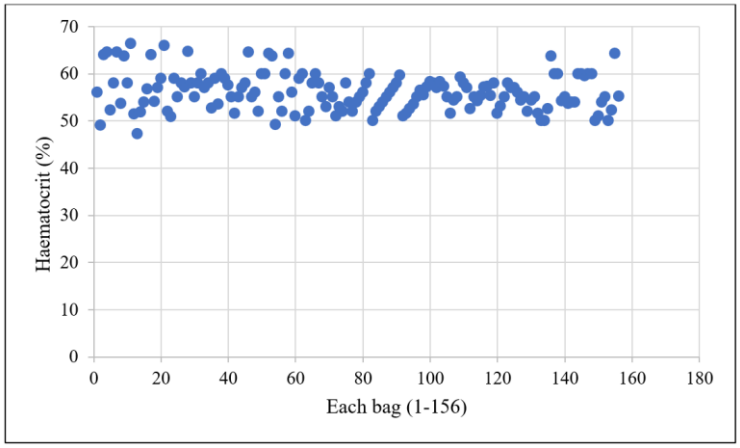

Figure 7: Haematocrit levels of red cell concentrate from 350 mL whole blood with additive solution (n = 156).

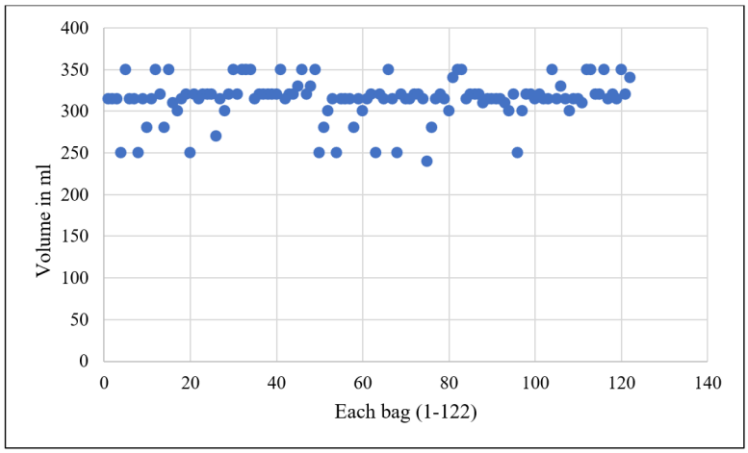

Figure 8: Volume of red cell concentrates from 450 mL whole blood with additive solution (n = 122).

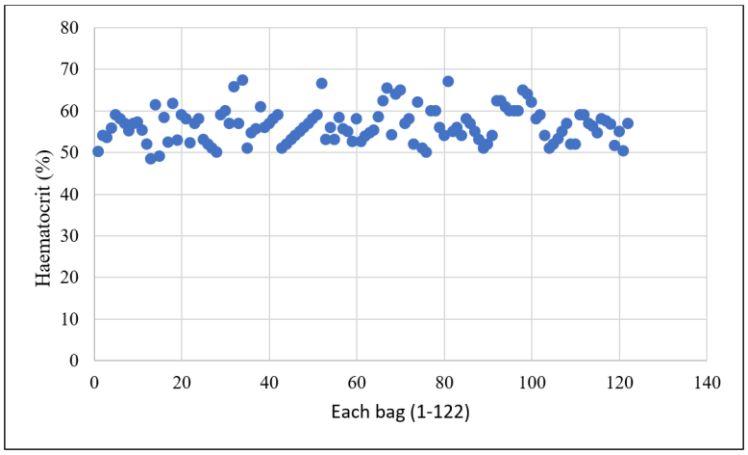

Figure 9: Haematocrit levels of red cell concentrate from 450 mL whole blood with additive solution (n = 122).

Similarly, Upadhyay et al. (2016) reported a mean volume of 285 ± 24.3 mL and haematocrit of 54 ± 4.2% for SAGM-prepared red cell concentrates [6, 7].

A 2022 study by Rathore et al. in Rawalpindi found haematocrit levels averaging 68.4 ± 4.8 g/dL [4]. Sultan et al. (2021) reported a mean haematocrit of 69.5 ± 7.24 g/dL in Southern Pakistan [1].

The quality control results in our centre align with the Technical Manual of Transfusion Medicine by the Directorate General of Health Services, Ministry of Health and Family Welfare, India (2023) [2].

This retrospective study may have limitations, including potential biases due to incomplete medical records and lack of generalizability. However, it offers valuable insights into red cell concentrate quality. Future prospective studies are needed to validate these results.

Maintaining high-quality blood products minimizes waste, reduces costs, and improves patient care by optimizing inventory management.

Conclusion

Our study demonstrated that the quality of red cell concentrates prepared from whole blood, with or without additive solution, complied with standard guidelines. Quality control of red cell concentrates should be carried out routinely as a standard operating protocol to ensure their efficacy, which may, in turn, minimize the risks associated with transfusion and subsequently inspire advancements in manufacturing methods. Analyzing data on the quality control of red cell concentrates can help identify areas for improvement, ensure compliance with regulations and standards, and ultimately improve patient safety. By evaluating data on the quality control processes, the effectiveness of manufacturing procedures can be assessed, and informed decisions to optimize blood centre operations can be made.

Abbreviations:

AAAB – American Association of Blood Banks

CPDA-1 – Citrate Phosphate Dextrose Adenine 1

IQC – Internal Quality Control

NABH – National Accreditation Board for Hospitals & Healthcare Providers

NACO – National AIDS Control Organisation

QC – Quality Control

SAGM – Saline, Adenine, Glucose, and Mannitol

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