Original Research

ASSESSMENT OF PLATELET CONCENTRATE QUALITY PARAMETERS AND CORRELATION WITH CLINICAL RESPONSE IN THROMBOCYTOPENIC PATIENTS

Dr. Khushbu Ashvinkumar Patel[1], Dr. Shruti Bharatbhai Patel[2], Dr. Sadhana Saraiya[3*], Dr. Jaymin Bhatt[4]

[1]Third Year Resident Doctor, Department of Pathology, SBKS MI and Research Institute Sumandeep Vidyapeeth, Vadodara, Gujarat, India.

[2]Third Year Resident Doctor, Department of Pathology, Narendra Modi Medical College, Ahmedabad, Gujarat, India.

[3*]Assistant Professor, Department of Pathology, Pramukh Swami Medical College, Karamsad, Gujarat, India.

[4]Professor, Department of Pathology, Nootan Medical College and Research Center, Sankalchand Patel University, Visnagar, Gujarat, India.

Email: [3*]sadhana2910@gmail.com

Corresponding Author: Dr. Sadhana Saraiya
Assistant Professor, Department of Pathology, Pramukh Swami Medical College, Karamsad, Gujarat, India.

ABSTRACT

Background: Platelet transfusion is a critical therapeutic intervention for thrombocytopenic patients, yet considerable variability exists in the quality of platelet concentrates (PCs) prepared by different methods. The relationship between measurable in vitro quality parameters and actual clinical transfusion response remains insufficiently characterized, particularly in resource-constrained settings where random donor platelet concentrates (RDPs) derived from whole blood remain the predominant platelet product. **Methods:** A prospective observational study was conducted. A total of 540 platelet concentrate units were evaluated for quality parameters including platelet count, volume, pH, swirling, white blood cell (WBC) contamination, and sterility. Clinical transfusion response was assessed in 186 thrombocytopenic transfusion episodes using the corrected count increment (CCI) at 1-hour and 24-hour post-transfusion intervals. **Results:** Mean platelet yield per unit was 6.14 ± 1.42 × 10^{10} for PRP-PCs, 7.28 ± 1.36 × 10^{10} for BC-PCs, and 32.4 ± 4.8 × 10^{10} for SDPs ($p < 0.001$). The 1-hour CCI was significantly higher in patients receiving SDPs (15,840 ± 4,260) compared to pooled BC-PCs (11,620 ± 3,870) and pooled PRP-PCs (8,940 ± 3,520; $p < 0.001$). A significant positive correlation was observed between platelet dose per unit body surface area and 1-hour CCI ($r = 0.58$; $p < 0.001$). Satisfactory transfusion response (1-hour CCI ≥ 7,500) was achieved in 82.3% of SDP transfusions, 68.5% of BC-PC transfusions, and 51.7% of PRP-PC transfusions ($p < 0.001$). **Conclusion:** Platelet concentrates prepared by apheresis and buffy coat methods demonstrate superior in vitro quality and yield significantly better clinical transfusion responses compared to PRP-derived concentrates. Platelet dose is the strongest predictor of clinical response, underscoring the importance of quality-controlled platelet production and dose-optimized transfusion strategies.

Keywords: Platelet Concentrate, Quality Control, Corrected Count Increment, Thrombocytopenia, Apheresis Platelets, Buffy Coat, Platelet-Rich Plasma, Transfusion Response.

INTRODUCTION

Platelet transfusion constitutes a cornerstone of supportive care in modern hematology, oncology, and critical care medicine, serving both therapeutic and prophylactic roles in the management of thrombocytopenic patients **[1]**.

The global demand for platelet components has increased steadily over the past two decades, driven by the expansion of intensive chemotherapy regimens, hematopoietic stem cell transplantation programs, complex cardiovascular surgeries, and trauma management protocols **[2]**. Unlike red blood cell concentrates, which have a shelf life of up to 42 days, platelet concentrates must be stored at 20–24°C under continuous agitation and have a maximum permissible storage duration of only five days in most jurisdictions, creating persistent challenges for inventory management and supply sufficiency **[3]**.

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Platelet concentrates may be prepared through three principal methodologies: (1) the platelet-rich plasma (PRP) method, in which whole blood is subjected to an initial low-speed centrifugation to generate PRP, followed by a high-speed centrifugation to pellet platelets; (2) the buffy coat (BC) method, in which whole blood undergoes a hard spin to separate the buffy coat layer, with subsequent pooling and light-spin centrifugation; and (3) single-donor platelet apheresis (SDP), in which platelets are selectively collected from a single donor using automated cell separator technology **[4]**. Each method yields products with distinct quantitative and qualitative characteristics, including differences in platelet count per unit, residual leukocyte contamination, plasma volume, activation state, and functional integrity **[5]**.

National and international standards—including those established by the American Association of Blood Banks (AABB), the Council of Europe, and the World Health Organization—specify minimum acceptable quality parameters for platelet concentrates **[6]**. However, compliance with these standards varies considerably across institutions and regions, and the relationship between adherence to in vitro quality benchmarks and actual clinical outcomes remains an area of active investigation **[7]**.

The corrected count increment (CCI), which normalizes the post-transfusion platelet count rise for both the platelet dose administered and the recipient's body surface area, is the most widely accepted metric for assessing clinical transfusion response and is used to identify platelet refractoriness when persistently suboptimal **[8]**.

Several factors influence clinical transfusion response beyond product quality, including recipient-related variables such as splenomegaly, disseminated intravascular coagulation (DIC), fever, active infection, concurrent medications, and alloimmunization against human leukocyte antigens (HLA) **[9]**. Nevertheless, accumulating evidence suggests that product-related factors—particularly the delivered platelet dose and the degree of storage-induced platelet lesion—exert a substantial and modifiable influence on transfusion outcomes **[10]**. Despite this recognition, comprehensive studies that simultaneously evaluate in vitro quality parameters across different preparation methods and systematically correlate these parameters with standardized clinical response metrics within the same patient cohort remain limited **[11]**.

The present study aimed to (1) assess and compare the in vitro quality parameters of platelet concentrates prepared by the PRP method, BC method, and single-donor apheresis, (2) evaluate the clinical transfusion response as measured by 1-hour and 24-hour CCI in thrombocytopenic recipients, and (3) determine the correlation between specific quality parameters and clinical transfusion efficacy.

MATERIALS AND METHODS

Study Design and Setting- This prospective observational study was conducted at tertiary care hospital. The blood center prepares platelet concentrates by all three methods and serves hematology-oncology, medical, surgical, and critical care patient populations.

Quality Assessment of Platelet Concentrates- A total of 540 platelet concentrate units were systematically evaluated: 200 PRP-derived random donor platelet concentrates (PRP-PCs), 200 buffy coat-derived platelet concentrates (BC-PCs), and 140 single-donor apheresis platelet concentrates (SDPs). Units were selected using systematic random sampling from routine daily production throughout the study period. Quality parameters assessed included: (1) unit volume measured gravimetrically; (2) platelet count per unit determined on an automated hematology analyzer (Sysmex XN-3000, Sysmex Corporation, Kobe, Japan); (3) residual WBC count measured by flow cytometry (BD FACSLyric, BD Biosciences, San Jose, CA, USA); (4) pH measured at expiry using a digital pH meter (Mettler Toledo SevenCompact, Columbus, OH, USA); (5) swirling grade assessed visually on a standardized light box and graded as present or absent; and (6) sterility testing performed by inoculating BacT/ALERT culture bottles (bioMérieux, Marcy-l'Étoile, France) on the day of expiry. Quality parameters were compared against national regulatory standards and Council of Europe guidelines.

Clinical Transfusion Response Assessment- A subset of 186 thrombocytopenic transfusion episodes was prospectively evaluated for clinical response. Eligible patients were adults (≥ 18 years) with thrombocytopenia (pre-transfusion platelet count $< 50 \times 10^9$/L) receiving platelet transfusions for either prophylactic (platelet count $< 10 \times 10^9$/L) or therapeutic indications. Transfusion episodes were classified by product type: pooled PRP-PCs (n = 60 episodes, each consisting of 4–6 pooled random donor units), pooled BC-PCs (n = 62 episodes, each consisting of 4–5 pooled units), and SDPs (n = 64 episodes).

Inclusion and Exclusion Criteria for Clinical Assessment- Inclusion criteria comprised: (1) age ≥ 18 years, (2) pre-transfusion platelet count $< 50 \times 10^9$/L, (3) no active hemorrhage at the time of transfusion assessment, and (4) availability of both 1-hour and 24-hour post-transfusion platelet counts. Exclusion criteria included: (1) documented HLA alloimmunization, (2) DIC (defined by International Society on Thrombosis and Haemostasis [ISTH] DIC score ≥ 5), (3) splenomegaly confirmed by imaging, (4) active sepsis at the time of transfusion, (5) concurrent administration of heparin or amphotericin B, and (6) massive transfusion protocols.

Calculation of Corrected Count Increment- The CCI was calculated using the standard formula:
CCI = (Post-transfusion count − Pre-transfusion count) × BSA (m^2) / Number of platelets transfused ($\times 10^{11}$)- Body surface area (BSA) was calculated using the Mosteller formula. A satisfactory response was defined as 1-hour CCI ≥ 7,500 and 24-hour CCI ≥ 4,500, consistent with internationally accepted thresholds.
Data Collection- Clinical data including diagnosis, indication for transfusion, concurrent medications, fever status, and pre- and post-transfusion platelet counts were documented prospectively.
Statistical Analysis- Data were analyzed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± SD and compared using one-way ANOVA with Tukey's post hoc test for multiple group comparisons. Categorical variables were presented as frequencies and percentages and analyzed using the chi-square test. Pearson correlation coefficients were calculated to assess the relationship between quality parameters and CCI. Multivariable linear regression was performed to identify independent predictors of 1-hour CCI. A p-value < 0.05 was considered statistically significant.

RESULTS

In Vitro Quality Parameters- Significant differences were observed across all three preparation methods for most quality parameters. SDPs demonstrated the highest mean platelet yield ($32.4 \pm 4.8 \times 10^{10}$), followed by BC-PCs ($7.28 \pm 1.36 \times 10^{10}$) and PRP-PCs ($6.14 \pm 1.42 \times 10^{10}$; $p < 0.001$). Residual WBC contamination was significantly lowest in SDPs ($0.18 \pm 0.12 \times 10^{6}$) and highest in PRP-PCs ($38.6 \pm 22.4 \times 10^{6}$; $p < 0.001$). The mean pH at expiry was maintained within acceptable limits (> 6.2) across all product types. Swirling positivity at the time of evaluation was observed in 97.1% of SDPs, 93.5% of BC-PCs, and 86.0% of PRP-PCs ($p < 0.001$). Bacterial culture positivity was detected in 2 PRP-PCs (1.0%), 1 BC-PC (0.5%), and 0 SDPs (0.0%; $p = 0.390$) (Table 1).

Table 1. In Vitro Quality Parameters of Platelet Concentrates by Preparation Method (N = 540)

Parameter	PRP-PCs (n = 200)	BC-PCs (n = 200)	SDPs (n = 140)	p-value
Volume (mL), mean ± SD	52.8 ± 8.4	58.6 ± 7.2	248.3 ± 32.6	< 0.001
Platelet count ($\times 10^{10}$/unit), mean ± SD	6.14 ± 1.42	7.28 ± 1.36	32.4 ± 4.8	< 0.001
Residual WBC ($\times 10^{6}$/unit), mean ± SD	38.6 ± 22.4	12.4 ± 8.7	0.18 ± 0.12	< 0.001
pH at expiry, mean ± SD	6.58 ± 0.24	6.72 ± 0.19	6.84 ± 0.16	< 0.001
Swirling positive, n (%)	172 (86.0)	187 (93.5)	136 (97.1)	< 0.001
Culture positive, n (%)	2 (1.0)	1 (0.5)	0 (0.0)	0.390
Meeting national standards*, n (%)	156 (78.0)	178 (89.0)	134 (95.7)	< 0.001

National standard: ≥ 5.5×10^{10} platelets/unit for RDPs; ≥ 3.0×10^{11} for SDPs; pH > 6.2; volume ≥ 50 mL.
Clinical Transfusion Response- Pre-transfusion platelet counts were comparable across the three groups ($p = 0.642$). The total platelet dose transfused was significantly higher in the SDP group ($32.4 \pm 4.8 \times 10^{10}$) compared to pooled BC-PCs ($30.6 \pm 5.4 \times 10^{10}$) and pooled PRP-PCs ($27.8 \pm 6.2 \times 10^{10}$; $p < 0.001$). The mean 1-hour CCI was significantly highest in SDP recipients (15,840 ± 4,260) compared to pooled BC-PC recipients (11,620 ± 3,870) and pooled PRP-PC recipients (8,940 ± 3,520; $p < 0.001$). The 24-hour CCI showed similar patterns across groups. Satisfactory 1-hour CCI (≥ 7,500) was achieved in 82.3% of SDP, 68.5% of BC-PC, and 51.7% of PRP-PC transfusion episodes ($p < 0.001$) (Table 2).

Table 2. Clinical Transfusion Response by Product Type (N = 186 Transfusion Episodes)

Variable	Pooled PRP-PCs (n = 60)	Pooled BC-PCs (n = 62)	SDPs (n = 64)	p-value
Pre-transfusion platelet count ($\times 10^{9}$/L), mean ± SD	12.8 ± 6.4	13.4 ± 7.1	13.1 ± 6.8	0.642
Number of units per episode, mean ± SD	4.6 ± 0.7	4.3 ± 0.6	1.0 ± 0.0	—
Total platelet dose ($\times 10^{10}$), mean ± SD	27.8 ± 6.2	30.6 ± 5.4	32.4 ± 4.8	< 0.001
1-hour platelet increment ($\times 10^{9}$/L), mean ± SD	18.4 ± 8.6	24.8 ± 9.4	32.6 ± 10.2	< 0.001

1-hour CCI, mean ± SD	8,940 ± 3,520	11,620 ± 3,870	15,840 ± 4,260	< 0.001
24-hour CCI, mean ± SD	4,280 ± 2,640	5,960 ± 2,780	8,420 ± 3,140	< 0.001
Satisfactory 1-hour CCI (≥ 7,500), n (%)	31 (51.7)	43 (69.4)	53 (82.8)	< 0.001
Satisfactory 24-hour CCI (≥ 4,500), n (%)	24 (40.0)	36 (58.1)	48 (75.0)	< 0.001
Bleeding cessation (therapeutic episodes), n/N (%)	8/14 (57.1)	12/16 (75.0)	14/17 (82.4)	0.264

Correlation and Regression Analysis- Pearson correlation analysis demonstrated significant positive correlations between total platelet dose per m² BSA and 1-hour CCI ($r = 0.58$; $p < 0.001$), between individual unit platelet count and 1-hour CCI ($r = 0.44$; $p < 0.001$), and between swirling positivity and 1-hour CCI ($r = 0.31$; $p < 0.001$). Residual WBC count showed a weak but significant negative correlation with 24-hour CCI ($r = −0.24$; $p = 0.001$). On multivariable linear regression, platelet dose per m² BSA ($\beta = 0.46$; $p < 0.001$), product type (SDP vs. PRP-PC; $\beta = 0.28$; $p < 0.001$), and absence of fever ($\beta = 0.19$; $p = 0.004$) were independently associated with 1-hour CCI (Table 3).

Table 3. Multivariable Linear Regression: Independent Predictors of 1-Hour CCI (N = 186)

Variable	Standardized B	95% CI	P-Value
Platelet Dose Per M² BSA (× 10^{10}/M²)	0.46	0.34 – 0.58	< 0.001
Product Type (SDP Vs. PRP-PC)	0.28	0.14 – 0.42	< 0.001
Product Type (BC-PC Vs. PRP-PC)	0.16	0.03 – 0.29	0.018
Absence Of Fever	0.19	0.06 – 0.32	0.004
Storage Age (Days)	−0.14	−0.27 – −0.01	0.032
Pre-Transfusion Platelet Count	−0.08	−0.21 – 0.05	0.214
ABO-Identical Transfusion	0.11	−0.02 – 0.24	0.092

Model adjusted $R^2 = 0.47$; $F = 22.8$; $p < 0.001$.

DISCUSSION

This prospective study provides a comprehensive assessment of platelet concentrate quality across three preparation methodologies and establishes clinically meaningful correlations between in vitro quality parameters and transfusion response in thrombocytopenic patients. Our findings demonstrate that single-donor apheresis platelets and buffy coat-derived concentrates exhibit superior quality profiles compared to PRP-derived products and that this quality differential translates into significantly better clinical transfusion outcomes as measured by the corrected count increment.

The observed platelet yields across the three preparation methods are consistent with established expectations and published literature. The mean yield of 6.14×10^{10} for PRP-PCs and 7.28×10^{10} for BC-PCs in our study aligns with reports from multiple blood centers worldwide. Pietersz et al. demonstrated that the BC method consistently yields approximately 15–20% more platelets per unit compared to the PRP method, attributable to more efficient platelet recovery during the two-step centrifugation process **[12]**. The significantly higher proportion of PRP-PC units meeting national quality standards (78.0%) compared to BC-PCs (89.0%) and SDPs (95.7%) raises important quality assurance concerns, particularly given that PRP-PCs constitute the majority of platelet products in many developing countries.

The substantially lower residual WBC contamination in SDPs (0.18×10^6) compared to BC-PCs (12.4×10^6) and PRP-PCs (38.6×10^6) carries critical clinical implications. Leukocyte contamination in platelet products is a recognized mediator of febrile non-hemolytic transfusion reactions, HLA alloimmunization, cytomegalovirus transmission, and immunomodulatory effects **[13]**. The TRAP trial established that leukoreduction significantly reduces HLA alloimmunization and platelet refractoriness rates **[14]**. In our study, the negative correlation between residual WBC count and 24-hour CCI ($r = −0.24$) provides additional evidence supporting the deleterious impact of leukocyte contamination on platelet survival and suggests that universal leukoreduction of whole blood-derived platelet products should be prioritized.

The clinical transfusion response data represent a central contribution of this investigation. The mean 1-hour CCI values of 15,840, 11,620, and 8,940 for SDPs, BC-PCs, and PRP-PCs, respectively, demonstrate a clear product-dependent gradient in transfusion efficacy. These values are consistent with multicenter data reported by the BEST Collaborative and other investigators **[15]**. The

PLADO trial established that prophylactic platelet transfusion efficacy is largely dose-dependent, with higher doses producing greater count increments but not necessarily superior bleeding prevention at standard prophylactic thresholds **[16]**. Our multivariable analysis corroborates this dose-response relationship, identifying platelet dose per m^2 BSA as the strongest independent predictor of 1-hour CCI ($\beta = 0.46$), which is consistent with the fundamental pharmacokinetic principles governing platelet transfusion therapy.

The independent predictive value of product type even after adjustment for platelet dose suggests that qualitative differences between preparation methods—including platelet functional integrity, activation state, and microparticle generation—influence clinical response beyond the simple quantitative dimension of platelet dose. Kerkhoffs et al. demonstrated that buffy coat-derived platelets exhibit lower activation markers (P-selectin, glycoprotein 53) and superior in vitro functional responses compared to PRP-derived platelets **[17]**, which may partially explain the superior clinical performance of BC-PCs independent of dose.

The negative independent association between storage age and 1-hour CCI ($\beta = -0.14$) is consistent with the well-characterized platelet storage lesion (PSL), a constellation of time-dependent biochemical, structural, and functional alterations that progressively compromise platelet viability and hemostatic efficacy during storage **[18]**. These changes include progressive loss of discoid morphology, decreased hypotonic shock response, mitochondrial dysfunction, cytokine accumulation, and shedding of surface glycoproteins. Aubron et al. conducted a systematic review confirming that increased platelet storage duration is associated with reduced CCI and potentially inferior clinical outcomes **[19]**. Our findings reinforce the importance of minimizing storage duration and prioritizing fresher products when clinically feasible.

The identification of fever as a significant negative predictor of transfusion response (absence of fever $\beta = 0.19$) highlights the clinical reality that non-immune consumptive factors frequently override product quality in determining transfusion outcomes. Slichter et al. comprehensively categorized clinical factors associated with platelet refractoriness and demonstrated that non-immune causes—including fever, infection, DIC, and medications—account for the majority of unsatisfactory transfusion responses **[20]**. This observation underscores the importance of addressing modifiable clinical factors alongside optimizing product quality to maximize transfusion efficacy.

Several limitations warrant acknowledgment. First, the observational design precludes definitive causal inferences regarding the superiority of one preparation method over another. Second, we excluded patients with known alloimmunization, splenomegaly, and DIC, which may limit the generalizability of our findings to these high-risk populations. Third, we did not perform comprehensive platelet function testing (aggregometry, flow cytometric activation markers, thromboelastography) on the evaluated concentrates, which would have provided deeper mechanistic insight into the quality-outcome relationship. Fourth, the sample size for clinical response assessment, while adequate for detecting CCI differences, was insufficient for evaluating hard clinical endpoints such as bleeding events or mortality. Finally, cost-effectiveness analysis comparing the three preparation methods was not undertaken and represents an important consideration for resource-constrained settings **[21]**.

CONCLUSION

This study demonstrates significant differences in the in vitro quality parameters of platelet concentrates prepared by the platelet-rich plasma, buffy coat, and single-donor apheresis methods, with apheresis and buffy coat products consistently exhibiting superior platelet yields, lower leukocyte contamination, better pH maintenance, and higher rates of compliance with national quality standards. These quality differences translate into clinically meaningful advantages, as evidenced by significantly higher corrected count increments and greater proportions of satisfactory transfusion responses in patients receiving apheresis and buffy coat-derived platelets compared to PRP-derived products. Platelet dose per unit body surface area emerges as the strongest independent predictor of clinical response, while product type, storage duration, and recipient fever status also exert significant independent influences on transfusion efficacy. These findings underscore the critical importance of rigorous quality control programs in blood banking, support the transition from PRP to buffy coat-based whole blood component preparation where apheresis capacity is limited, and advocate for dose-optimized transfusion strategies tailored to individual patient characteristics to maximize the clinical benefit of platelet transfusion therapy.

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