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Hematological Changes in the Platelet Apheresis Donors - An Observational Study

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KEYWORDS

Single Donor platelets, Plateletpheresis, Hematocrit, platelet, donor

ABSTRACT:

Introduction: The demand for platelet concentrates is increasing for treating patients in clinics such as oncology. Single Donor Platelets (SDPs) collected through apheresis offer a lower risk of transfusion-related complications.

Objectives: This observational study aims to evaluate hematological changes in donors before and after platelet donation via apheresis, shedding light on donor safety and eligibility criteria.

Methods: This pilot study included 30 plateletpheresis procedures carried out between August and October 2023, with all participants providing informed consent. Donors underwent comprehensive screening, which assessed medical history, hematological parameters, and infectious disease markers. The procedures were conducted using the Trima Accel cell separator, following both standard operating procedures and manufacturer guidelines. Detailed records of donor information and procedural specifics, including hematological values and platelet yield, were meticulously maintained. To ensure donor safety, prophylactic oral calcium was administered, and any adverse reactions were promptly managed in accordance with departmental protocols.

Results: All donors were male, with an age range of 18-45 years. Blood group distribution among donors was O+ve (12), A+ve (6), B+ve (5), AB+ve (4), B-ve (1), O-ve (1), and AB-ve (1). The mean fall in platelet count after donation was 50,833/mm^3. The overall mean fall in hematocrit was 1.16%, with a range of 0.5-2%. For donors with a platelet yield of 3.0x10^{11}, the average hematocrit reduction was 1.13%, whereas for donors with a yield of 3.5x10^{11}, the reduction was 1.56%.

Conclusions: Automated cell separators have significantly improved SDP quality and collection efficiency. The correlation between platelet yield and pre-donation platelet count underlines the importance of personalizing collection parameters.

1. Introduction

Platelets collected using an apheresis cell separator are commonly referred to as single donor platelets (SDP). In medical settings, single donor platelet transfusions are typically recommended for preventing and treating bleeding in patients with low platelet counts or issues with platelet function [1].

The demand for platelet concentrates is consistently rising, especially in specialized clinics like oncology, clinical hematology, critical care medicine, hepatology, and transplant units [2]. 28%-34% patients show platelet refractoriness who underwent previous multiple blood transfusions [3]. In contrast to random donor platelets (RDP) obtained from whole blood, Single Donor Platelets (SDPs) offer a greater number of platelets to the recipient, lower risk of transfusion related transmitted infections, and alloimmunization, platelet refractoriness, and other adverse transfusion-related events [4].

There is a growing preference for utilizing SDPs to support patients with thrombocytopenia. The collection of SDPs through the apheresis procedure, known as plateletpheresis, is generally regarded as safe for donors and has minimal complications [5].

The new generation cell separators allow the easy separation of platelets with minimal manipulation [6]. A variety of apheresis machines are commercially

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available, operating on the principle of centrifugation. Extensive research has shown that these machines are user-friendly and donor-friendly, ensuring the optimization of platelet quality [7].

In many centres, unfortunately, there have been cases of donors experiencing mortality. This underscores the importance of not just focusing on complications, but also closely monitoring changes in laboratory test indicators and the overall well-being of donors' post-donation [8].

Examining the safety of apheresis donors is crucial in the field of blood donation. This study focuses on monitoring hematological changes in apheresis donors, providing insights into the physiological impact of these procedures. The findings could have substantial implications for donor care, eligibility criteria, and the overall safety of apheresis donations, potentially raising the standards of care for these generous individuals who contribute vital blood components to patients in need.

2. Objectives

To evaluate changes in hematological parameters like platelet count and hematocrit before and after platelet donation through the apheresis procedure.

3. Methods

This pilot study included 30 plateletpheresis SDP procedures conducted from August 2023 to October 2023. All procedures were performed on eligible donors who provided informed consent.

Donor Selection

Following registration, all donors underwent screening for age, weight, blood group, medical history, drug history, vein condition, and other selection criteria. Donors who met the initial screening criteria had whole blood samples collected for mandatory laboratory screening as per national guidelines for plateletpheresis.

Donor Sampling

Whole blood samples in EDTA and clotted vials were collected before the plateletpheresis procedure. Hematological parameters such as platelet count (PLT), hemoglobin (Hb), hematocrit (Hct), and white blood cell (WBC) count were measured using a calibrated automated cell counter (5-part CBC Analyser). Blood group and antibody screening were confirmed, followed by testing for infectious markers including anti-HIV 1 & 2, anti-HCV, HBsAg, syphilis, and malaria. Anti-HIV 1 & 2, anti-HCV, and HBsAg tests were conducted using the automated VITROS ECiQ immunodiagnostic system based on enhanced chemiluminescence technology. Syphilis was tested using rapid qualitative immunochromatography, while malaria antigens for Plasmodium falciparum and Plasmodium vivax were assessed via rapid qualitative chromatographic immunoassay.

Procedure and Donor Safety

Only donors who passed the screening test were selected for the plateletpheresis procedure. Plateletpheresis procedures were conducted using the Trima accel cell separator. All plateletpheresis procedures were conducted following the manufacturer's instructions and departmental standard operating procedures (SOPs) using recommended apheresis kits. The endpoint of each procedure was determined by the target platelet yield per unit. Donor information, including name, registration number, blood group, age, gender, weight, hematological values, and plateletpheresis procedure details, such as kit information, total blood volume processed, anticoagulant (CPDA-1) volume used, procedure time, blood flow rate, and collection efficiency of machines (PLT yield/Total volume of blood processed), was recorded for each procedure in the procedure register. All donors were given prophylactic oral calcium (1000 mg) and were provided with a detailed explanation of the procedure before its commencement. Donors were encouraged to report any discomfort during or after the procedure to the apheresis team. Any donor adverse reactions were managed according to departmental SOPs and documented accordingly.

Quality Control of SDP

Approximately 1 ml samples from each bag were collected in EDTA vials after thorough segment stripping to ensure a representative product from the bag. All samples were mixed thoroughly and subjected to quality parameter measurements such as volume, Hct, PLT, RBC, and WBC counts.

4. Results

As this study is a pilot study, a sample size of 30 male donors was selected, with age distribution as follows: 11 donors in the 18-25 years range, 14 donors aged 26-35

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years, 4 donors aged 36-45 years, and 1 donor older than 45 years (Figure 1). The mean weight of the donors was 73.53 kg, and the average height was 170.7 cm. Blood group distribution revealed 12 donors with O+ve, 6 with A+ve, 5 with B+ve, 4 with AB+ve, 1 with B-ve, 1 with O-ve, and 1 with AB-ve (Figure 2).

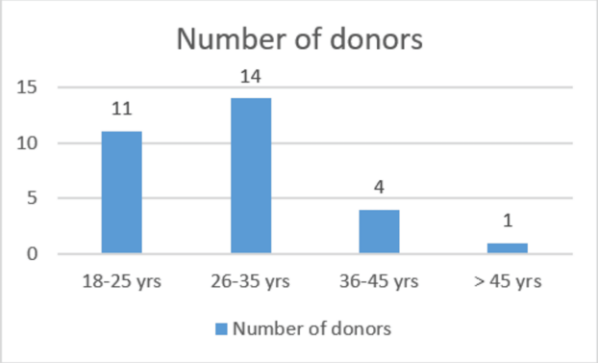

Figure 1. Distribution of donors according to age.

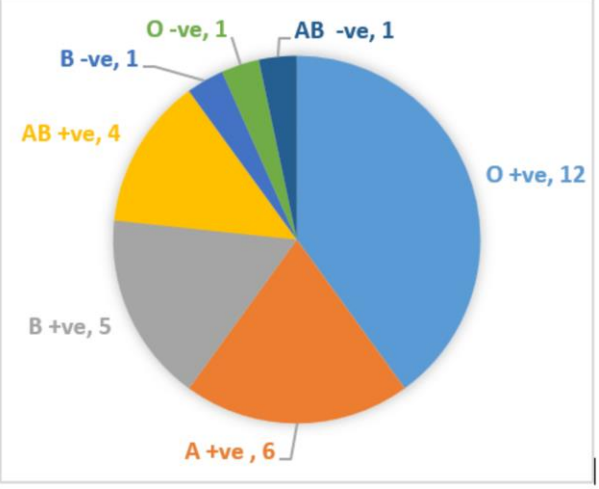

Figure 2. Distribution of donors according to blood group.

Platelet Variation After Donation

The total platelet count before donation exhibited a range of 223,000-493,000/mm3. Following donation, the overall fall of platelet count was 35,000-66,000/mm3, with an average fall of 50,833/mm3. The reduction in platelet count was directly proportional to the targeted platelet yield. For donors with a platelet yield set at 3.0x1011, the platelet fall ranged from 35,000-64,000/mm3, with an average reduction of 48,095/mm3. Meanwhile, for those with a yield set at 3.5x1011, the platelet fall ranged from 51,000-66,000/mm3, with an average reduction of 57,220/mm3 (Table 1).

Platelet Yield	No. of Donors	Range of platelet count before donation	Range of platelet fall after donation	Mean fall in platelet count
3.0×10^{11}	21	2,23,000 to 4,93,000	35,000 to 64,000/ mm^3	48,095/ mm^3
3.5×10^{11}	09	2,25,000 to 4,21,000	51,000 to 66,000/ mm^3	57,220/ mm^3

Table 1. Variation in Platelet Count as per platelet yield.

Platelet Yield	No. of Donors	Range of Hematocrit before donation (in %)	Range of Hematocrit fall after donation (in %)	Mean fall in Hematocrit (in %)
3.0×10^{11}	21	37.7 to 48.0	0.8 to 2	1.13
3.5×10^{11}	09	38.3 to 49.5	0.5 to 1.6	1.56

Table 2. Variation in hematocrit as per platelet yield**.**

Hematocrit Variation After Donation:

The range of hematocrit before donation spanned 37.7%-49.5%. Post-donation, the overall fall in in hematocrit was 0.5-2%, with a mean reduction of 1.16%. For donors with a platelet yield set at $3.0x10^{11}$, the hematocrit fall ranged from 0.8-2%, with an average reduction of 1.13%. On the other hand, for those with a yield set at $3.5x10^{11,}$ the hematocrit fall ranged from 0.5-1.6%, with an average reduction of 1.56%.

5. Discussion

This pilot study, focusing on the evaluation of changes in hematological parameters pre- and post-platelet donation through the apheresis procedure, observed a significant

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reduction in platelet count by an average of 50,833/mm³. However, it is considerably less than the post-apheresis decrease reported by Enein et al., who observed a decrease of 53.6 ± 26.3/mm3, suggesting variability in the impact of apheresis across different settings and methodologies [9].

The targeted platelet yield in our study was set at 3.0 x 10^{11}, which is contrasted by the yields reported in other studies. For instance, Hitzler WE et al. reported a mean platelet yield of 4.5 ± 0.8 x 10^{11}/L, and Chopra et al. found the mean platelet yield in single donor platelets (SDP) to be 4.09 ± 1.15 × 10^{11}. These discrepancies highlight differences in procedural efficiencies and donor selection criteria across studies [10,11].

Our study's findings on the direct proportionality between the reduction in platelet count and the targeted platelet yield mirror the significant correlation between pre-donation platelet count and yield observed by Chopra et al. and the positive correlation reported by Enein et al. between Platelet pre-donation count and yield (r = 0.512). This reinforces the predictive value of pre-donation platelet counts for yield outcomes [9,11].

In terms of hematocrit changes, our study noted a mean reduction of 1.16% post-donation. This is in line with the findings of Rajput et al., who reported a non-significant decline in Hct (p = 0.44), indicating that the impact of plateletpheresis on hematocrit levels is generally minimal and transient. This suggests that the procedure is safe in terms of maintaining red blood cell volume [12].

Thokala et al.'s observation of a progressive post-procedure increase in platelet count across all groups underscores the body's ability to recover post-donation. Our study did not measure platelet count recovery over time, presenting an area for future research to better understand the timeline and mechanisms of hematological recovery post-apheresis [13].

This reduction in platelet count is within the range but notably distinct from the findings of Syal et. al., who documented a decrease in post-donation mean platelet count of 70,800/mm³. Moreover, the increase in post-procedural mean hemoglobin levels reported by Syal et al., with a statistically significant increase of 0.14 g/dl, contrasts with the expectation of stable or declining levels post-donation. This observation may indicate procedural or physiological differences that merit further investigation [14].

Comparatively, our study enriches the existing literature by providing detailed insights into the hematological impact of plateletpheresis in a specific donor population. It also highlights the need for further research to explore the influence of factors such as blood group on yield outcomes, as our study did not find a significant impact, aligning with Ugwu et al.'s findings [15].

A key difference underscored by our findings is the direct correlation between targeted platelet yield and the magnitude of platelet reduction, a detail that complements the existing literature by providing a focused examination of the physiological implications of yield targets on donor safety and recovery. Furthermore, our study adds to the discourse on the safety of plateletpheresis by documenting minimal changes in hematocrit levels, reinforcing the procedure's safety profile as noted by Rajput et al. but within the context of a different target yield and donor demographic [12].

The key takeaway from our study is the affirmation of plateletpheresis as a safe procedure for donors, with predictable hematological outcomes that are directly influenced by the target platelet yield. This insight is crucial for optimizing donor selection criteria and procedural settings to balance the demands of platelet supply with donor safety and well-being. Our findings suggest that while higher yield targets are achievable and have been documented in the literature, a conservative approach to yield targeting can still meet clinical needs without compromising donor health, offering a strategic perspective for blood donation centers aiming to maximize both donor safety and the efficiency of platelet collection.

Our study being a pilot study, had been performed on a sample size of 30 donors, which happens to be a limitation. Study with a larger sample size may help establish more accurate correlation between the various hematological parameters among plateletpheresis donors.

Conclusion: The use of automated cell separators for platelet collection has significantly improved the quality of Single Donor Platelets (SDP). These machines are more efficient at harvesting platelets while reducing the number of white blood cells and red blood cells in the

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collection. They also streamline the process, use fewer anticoagulants, enhance donor safety, and encourage repeated donations. To mitigate citrate-related issues and following previous research recommendations, apheresis centers can administer 1000-2000 mg of oral calcium to donors at least 30 minutes before the procedure.

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