

Haematological Changes in Donors Post Apheresis

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ABSTRACT

Introduction: The productivity, quality of platelet apheresis collection has improved because of the considerable advancement in the automated cell separators. Automated cell separators have lot of sizeable scientific advances, but the alertness has been centered to Platelet Concentrates (PCs) quality than on safety of donor.

Aim: To find the changes in haematological parameters and the consequences of apheresis and plateletpheresis on donor's health.

Materials and Methods: It was observational cross-sectional study done in laboratory at RL Jalappa Blood Bank, Tamaka, Kolar, Karnataka, India. The study was done from March 2019 to August 2020. A total of 300 healthy donors (plateletpheresis donors) were involved in the study. The plateletpheresis (Haemonetics MCS), predonation and postdonation haematological parameters such as haemoglobin concentration, Haematocrit (Hct), platelet, white and red blood cell count were calculated in all donors. The samples for Complete Blood Count (CBC) were secured from the donors, at the beginning and end of the procedure. Postdonation haematological parameters such as platelet count, haemoglobin, haematocrit, White Blood Cells (WBC), Red Blood Cells (RBC)

counts of the donor was inscribed and comparison was done with the pre donation haematological parameters. Quality control of all Single Donor Platelet (SDP) products was done. All donors were evaluated for adverse donor reactions. The mean pre and post plateletpheresis values comparison was done utilising paired t-test. Statistical analysis was accomplished utilising Statistical Package for the Social Sciences (SPSS) software version 16.0.

Results: Platelet count, haemoglobin, WBC count, RBC count and haematocrit were jotted down from 262 donors and a significant decrease was noticed in these parameters postdonation. Donor parameter platelet count (lac/ μ L) value was decreased from 273.57-224.28 whereas WBC count (cu/mm) predonation value decreased from 9.91-8.86 Postdonation, haemoglobin (g/dL) value decreased from 14.46-12.91, haematocrit (%) decreased slightly from 45.19-44.19, RBC count (million/ mm^3) decreased from 5.21-5.01. This concluded that the values decreased postdonation.

Conclusion: The study conducted was safe from donor's point of view. SDP is very effective in treatment of thrombocytopenia and is safe from recipient's point of view.

Keywords: Plateletpheresis, Single platelet donor, Thrombocytopenia

INTRODUCTION

The productivity, quality of platelet apheresis collection has improved because of the considerable advancement in the automated cell separators [1]. Automated cell separators have lot of significant scientific advances, but the alertness has been centered to PCs quality than on safety of donor. Safety subject with contemplation to postprocedure platelet count or concentration of haemoglobin with other haematological profile in donors undertaking plateletpheresis procedure has slightest exploration. A thorough search on literature provided contentious data that indicated an increase in haemoglobin concentration, haematocrit, WBC count after plateletpheresis in one study by Beyan C et al., [2]; while on the contrary other studies had shown decline in these parameters [1]. Study was accomplished to note the sequel of automated plateletpheresis on normal haematological profile on healthy donors and to ascertain that haematological changes had any significant clinical upshot [3]. Platelets were first recognised in 1889, there have been uninterrupted progress in basic understanding of function of platelets and its use in bleeding disorders. First successful attempt to increase platelet count in thrombocytopenic subjects by whole blood transfusion described by Duhr in 1910. Transfusion of platelets is primary modality for thrombocytopenia due to various etiologies. Thrombocytopenia can be due to quantitative or qualitative defect. Qualitative defect means defect in platelet, quantitative means decline in platelet count either due to chemotherapy or primary effect. Three types of PCs are available for transfusion: One Random Donor Platelets (RDP) (Platelet Rich Plasma- Platelet Concentrate (PRP-PC)), Buffy coat poor-platelet concentrate (BC-PC) and other is SDPpheresis (Apheresis-PC) mustered from thrombocytopenic donors by assistance of an automated cell separators. Basic principle

behind separation of components from the whole blood is each component has its specific gravity. By doing centrifugation each component separation and removal is done. This allows transfusion of component in accordance to requirement of the patient. PCs shelf life in platelet storage bags is five days at $22\pm 2^\circ\text{C}$ with continuous agitation. Platelets are subjected to storage changes such as from collection, processing, intrinsic condition in the patient affecting therapeutic welfare to the recipient.

Apheresis

This procedure involves withdrawing whole blood from a donor/patient, separating into individual components for removing one particular component. The remaining blood components then are re-introduced back into the bloodstream of the patient or donor [3]. Apheresis technology routinely utilised to obtain platelets as therapeutic dose of platelets (equal to six whole blood-derived platelet units) or three therapeutic doses (equal to 18 whole blood (WB)-derived units) can be obtained via single apheresis donation. Most common ground for the urging requisite for plateletpheresis is because of increased cognisance about specific component therapy, increased acknowledgement regarding the risk associated in regard to blood transfusion amidst the clinical specialities. Generally, apheresis is well-tolerated, however some adverse reactions to donor can occur after the procedure which includes local reactions such as haematoma, swelling, pain, thrombophlebitis and systemic reaction mainly vasovagal shock. Hence, the prevention of these adverse donor reaction and changes in the haematological values is of paramount importance for donors safety. According to American Association of blood bank, the requirement of platelet in apheresis platelet component is 3×10^{11} platelets in 90% of sampled units.

The aim of the study was to evaluate the haematological changes that transpired post plateletpheresis in apheresis donor and compare pre and postdonation haematological changes in donors and to determine the consequences of apheresis, plateletpheresis on donor's health.

MATERIALS AND METHODS

It is observational cross-sectional study done in laboratory at RL Jalappa Blood Bank, Tamaka, Kolar, Karnataka, India. The study was done from March 2019 to August 2020. The Ethics Committee Approval was obtained for this study, IEC No. DMC/KLR/IEC/803/2019-20. A total number of donors sorted out for the study were 300, out of which only 262 were eligible.

Inclusion criteria: Inclusion criteria included donors from age between 18-50 years with Platelet count $>200 \times 10^9/L$, having prominent antecubital vein and who necessarily gave informed consent given informed consent.

Exclusion criteria: Exclusion criteria included hypertensive patients with Blood Pressure (BP) $>150/100$ mmHg, Platelet count $<200 \times 10^9/L$, serological test positive for transfusion transmitted infections for example Human Immunodeficiency Virus (HIV), Hepatitis B and C Viruses (HBV and HCV) and syphilis, weight less than 50 kg and pregnant women.

For CBC Blood samples were withdrawn before and after the procedure from the donors and the samples processed on HAEMONETICS system, the anticoagulant used was Anticoagulant Citrate Dextrose solution A (ACD-A). Postdonation haematological parameters that is platelet count, haemoglobin, WBC count, RBC count and haematocrit values were inscribed from the donor on SYSMEX XN-550 and was compared to that of the predonation haematological parameters. Quality control of all SDP products was done. All donors were observed for adverse donor events no major donor events were noted minor adverse events were noted in few cases such as headache and giddiness.

STATISTICAL ANALYSIS

Data events were presented in the form of mean and standard deviation. The mean pre and post plateletpheresis values comparison was done utilising paired t-test. Statistical analysis was accomplished utilising statistical software SPSS version 16.0. A p-value less than 0.05 was considered significant.

RESULTS

In this study, 262 donors were put through for apheresis out of which 256 were males and six were females. Donors were divided into 5 groups according to the range of platelets. Group 1 with platelet count 150 to 200 where the number of donors were 19, group 2 with platelet count 201-250 had total number of 45 donors, group 3 with platelet count 251-266 with 108 donors. Group 4 had 61 donors with platelet count between 301-350 and group 5 with platelet count more than 351 which had a total of 29 donors. It was noticed that the most of donors had platelet count between 2,51,000 to 3,00,000 [Table/Fig-1].

Donor's group	Platelet range (lac/ μ L)	Number of donors	Percentage of donors
1	150-200	19	7.2%
2	201-250	45	17.1%
3	251-300	108	66.6%
4	301-350	61	23.2%
5	>351	29	11%

[Table/Fig-1]: Number of donor distribution as per the platelet count.

Mean value of the product yield of different groups of donors were computed along with the average platelet count and was further analysed with each other. It was found that platelet count which

was more than 3,51,000 gave the highest product yield. And platelet count between 150-200, gave the lowest. Hence, it was concluded that higher platelet count gave more platelet yield [Table/Fig-2].

Groups	Donor platelet count (lac/ μ L)	Product yield	Average platelet count
1	150-200 (19)	2.46	791
2	201-250 (45)	3.89	1099
3	251-300 (108)	4.27	1413
4	301-350 (61)	4.36	1499
5	>351 (29)	4.9	1522

[Table/Fig-2]: Average platelet count and product yield of the donors.

The haematological parameters like Platelet count (lac/ μ L), WBC count (cu/mm), Haemoglobin (g/dL), haematocrit (%) and RBC count (million/ mm^3) were calculated and a decrease of 18.01%, 10.59%, 10.71%, 2.21% and 3.83% in their respective count was noted, postdonation in the donors was of substantial statistical difference as p-value is <0.001 [Table/Fig-3,4].

Donor parameter	Pre donations		Post donation		p-value
	Mean	SD	Mean	SD	
Platelet count (lac/ μ L)	273.57	67.23	224.28	45.86	<0.001
WBC count (cu/mm)	9.91	1.45	8.86	1.09	0.002
Haemoglobin (g/dL)	14.46	2.34	12.91	1.47	0.003
Haematocrit %	45.19	4.4	44.19	3.9	0.355
RBC count (million/ mm^3)	5.21	1.89	5.01	1.03	0.612

[Table/Fig-3]: Pre donation and post donation Haematological parameter change (mean and standard deviation with p-value) [SD: Standard deviation] The mean pre- and post plateletpheresis values comparison was done utilising paired t-test.

Donor parameter	Percentage decrease
Platelet count (lac/ μ L)	18.01%
WBC count (cu/mm)	10.59%
Haemoglobin (g/dL)	10.71%
Haematocrit%	2.21%
RBC count (million/ mm^3)	3.83%

[Table/Fig-4]: Percentage decrease in haematological parameters post donation.

DISCUSSION

Platelets are small, enucleated haematopoietic lineage of megakaryocytes produced in bone marrow and helps in maintenance of primary haemostasis, blood flow in the blood vessel by two major mechanisms that is platelet adhesion and platelet aggregation [4]. Platelets transfusion can be done either for a remedial or prophylactic cause. Most of the transfusions are given to prevent bleeding in thrombocytopenic patients. The usual dose of platelet is one apheresis unit (SDP) or a pool of four to six concentrates from individual units of whole blood [5]. Numerous studies on automated plateletpheresis were directed for instigating the quality of PCs with respect to platelet count of the donor, nevertheless there are safety matters in relation to platelet count postdonation, haemoglobin values and decrease in other haematological parameter undertaking plateletpheresis and there is slightest exploration. With the Idea of donors undertaking plateletpheresis it can lead to substantial decline in haematological parameters, it was required to study and evaluate the sequel of automated plateletpheresis on haematological parameters on donors and its implication [6]. The advantage of SDP is that it reduces the number of donor exposure to 4-6 folds in terms of transfusion transmitted infection and single donor can produce a sufficient dose for transfusion. Each country has a separate rule for donor and recipient. In general, the donor must weigh more than 50 kg, have platelet count more than $150 \times 10^9/L$ [7]. Maximum platelet that can be extracted in one sitting is 50% as they can be replenished in about three days in the body [1]. In this study, the sample size was 300, out of which only 262 donors could participate in the study as only the required criteria

were only fulfilled by them. The donor's were divided into five groups based on the predonation platelet count and further analogies between predonation platelet count and product yield was studied. A significant increase in the product yield was found if the pre donation platelet count was more than 2,51,000 with 198 out of 262 donors giving platelet yield more than 1400. There was further decrease in platelet count in donors after donation which was approximately around 18%. The other haematological parameters such as WBC count (cu/mm), haemoglobin (g/dL), haematocrit (%), RBC count (million/mm³) were prepensed and values noticed were 10.59%, 10.71%, 2.21% and 3.38% decrease in their respective count, postdonation in the donors was found. This reduction in haematological values raised a safety issue for donors. The adverse effect with regards to these reductions such as thrombocytopenia and anaemia has to be prevented. The mean value of predonation and postdonation haemoglobin was 14.46 which reduced to 12.91 postdonation, giving a reduction of 10.71%. Similarly, predonation WBC count mean value was 9.91 and postdonation count was 8.86, showing reduction of 10.59% of the value. With these results, it be concluded that preinct significant reduction in platelet count which was of substantial statistical significance. Decrease was also seen in other parameters such as haemoglobin and WBC count which was statistically significant with p-value 0.003 and 0.002, respectively. Hence, the procedure should be carefully monitored in the donors who undergo apheresis on a regular basis. This will lead to prevention of artificial anaemia and thrombocytopenia among the donors [8]. In a similar study by Das SS et al., it was concluded that haemoglobin concentration, platelet count (lac/ μ L), WBC count (cu/mm) and haematocrit (%) were decreased significantly in donors postprocedure in donors [1]. In other study by Khurshid I et al., the similar results were concluded, that is a significant fall in haemoglobin, platelet, haematocrit and RBC count (million/mm³) but the changes in WBC count (cu/mm) were not that significant [3]. In study done by Atluntas F et al., also showed decline in haemoglobin (g/dL) value predonation 15.6 to postdonation 15.4, decline in haematocrit (%) value from predonation 44.5%-41.4% postdonation, platelet count (lac/ μ L), also reduced from predonation 198 \times 10⁹/L-144 \times 10⁹/L postdonation, WBC count (cu/mm) reduced from 6.95 \times 10⁹/L-6.6 \times 10⁹/L [9].

The study done by Tendulkar A and Rajadhyaksha SB, also showed postdonation decrease in haemoglobin (g/dL), WBC count (cu/mm), platelet count (lac/ μ L), haematocrit values (%). Values observed in the study showed haemoglobin (g/dL) value decreased from 13.7-13.4, haematocrit (%) decreased from 41.9%-40.6%, platelet count (lac/ μ L) decreased from 255.2 \times 10⁹/L-176.8 \times 10⁹/L, WBC count (cu/mm) decreased from 6.6 \times 10⁹/L-6.0 \times 10⁹/L from predonation to postdonation values [10]. In present study, among the recipient very few that are only three recipients had reaction which later subsided with antihistamines. Transfusion Related Acute Lung Injury (TRALI) and Febrile Non-Haemolytic Transfusion Reactions (FNHTR) are the major life threatening reactions in the recipient, no cases of TRALI and FNHTR was recorded in the recipients in this study [11-13].

Limitation(s)

It could have been expedient to perform daily haematological parameter evaluation postdonation for several days for assessing platelets recovery trends, but because of logistic issue and inconvenience for the donors it was not possible to perform daily haematological parameters for several days.

CONCLUSION(S)

From this study, it was found that in a regular, average, normal, healthy individual the haematological parameters decreases postdonation causing anaemia and thrombocytopenia, which can be overcome by selection of appropriate healthy donors, careful monitoring of donors and strict quality controls for accurate reporting and quality control assurance. These particulars could be of utility in constructing postdonation range further helping in circumventing donor suitability for ensuing donation. Haematological parameters should be contemplated cautiously in donors who are undertaking abiding regular apheresis. In present study, donor safety was ascertained during the procedure. As there was significant decline in post haematological parameters, donor had remarkable clinical presentation. To forestall the adverse events for well being of donors, technical personnel training, procedure done under custody transfusion medicine specialists, close follow-up, of these donors is needed.

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