

**Original Article:****Changes in pre- and post-donation haematological parameters in plateletpheresis donors**

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**ABSTRACT**

**Background:** Recently the use of single donor platelet (SDP) concentrates has grown steadily due to its employment in chemotherapy protocols. Technical advances in automated cell separators have substantially improved the productivity and quality of the collection of apheresis platelets.

**Methods:** We prospectively studied 90 healthy donors who volunteered for plateletpheresis. We compared the pre- and post-plateletpheresis haematological values, namely, haemoglobin (Hb), haematocrit, platelet count, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, platelet distribution width (PDW), red blood cell count, white blood cell (WBC) count and mean platelet volume (MPV) in all of them.

**Results:** Following plateletpheresis a significant decrease in pre- and post-donation Hb (g/dL) ( $14.8 \pm 1.097$  Vs  $14.5 \pm 1.4$ ;  $p=0.002$ ); haematocrit (%) ( $43.29 \pm 6.62$  Vs  $41.64 \pm 4.96$ ;  $p=0.045$ ); platelet count ( $\times 10^9/L$ ) ( $280.34 \pm 54.55$  Vs  $175.58 \pm 44.56$ ;  $p < 0.001$ ); WBC count ( $\times 10^3/\mu L$ ) ( $8.28 \pm 1.88$  Vs  $6.95 \pm 1.76$ ;  $p < 0.001$ ); and PDW (fL) ( $15.96 \pm 1.38$  Vs  $4.96 \pm 0.67$ ;  $p=0.053$ ) and a slight rise in MPV (fL) ( $8.61 \pm 0.77$  Vs  $8.72 \pm 0.83$ ;  $p=0.067$ ) were observed. However, none of them developed clinical manifestation of anaemia or thrombocytopenia.

**Conclusions:** Close monitoring and follow-up for these donors is indicated to prevent unfavourable events caused by these changes.

**Key words:** *Plateletpheresis, Blood donor, Haemoglobin, Platelet count*

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**INTRODUCTION**

Apheresis is a Greek word that means to 'separate' or 'remove'. In apheresis, blood is withdrawn from a donor or a patient in anticoagulant solution and separated into components. One or more components are retained and the remaining constituents are returned to the individual.<sup>1,2</sup> Plateletpheresis is a procedure where the whole blood is processed from a donor and the platelets alone are separated and the remaining blood components are returned back to the donor. The cell separator has been used as a primary tool to collect platelet concentrates. Technical advances in automated cell separators have substantially improved the productivity and quality of the collection of single donor platelets.<sup>3</sup> Recently the use of single donor

platelet (SDP) concentrates has grown steadily due to its employment in chemotherapy protocols. This is especially due to lower alloimmunization and transmission of viruses to patients afforded by reduced donor exposure.<sup>4-8</sup> It is also used in platelet refractory patients where there is need of human leukocyte antigen (HLA) matched or human platelet antigen matched components are warranted. Wherever platelets transfusions are required, SDPs can be used as it provides an adequate therapeutic adult dose. Increasing demand for platelet transfusion implies the need to recruit greater numbers of donors, and ensuring the safety of the donors is a crucial factor in recruitment.

As nearly all red blood cells (RBC) and white blood cells (WBC) can be returned to the donor,

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it is common practice to repeat apheresis donations at close intervals. This has raised concerns that frequent collection of blood cells, in particular platelets, could result in large cell losses that could lead to transient clinically significant problems in donors.<sup>9</sup>

Now a days, the cell separators can yield high-dose plateletpheresis, resulting in up to four units of apheresis platelets for transfusion to patients.<sup>9</sup> However, concerns regarding the safety of platelet donors run contrary to these interests and technical possibilities. This can be easily investigated by measuring the total platelet counts of normal donors before and after plateletpheresis. As these hematological changes may induce clinical implications to the donor such as thrombocytopenia and anaemia, the present study was done to investigate the changes in haematological values after plateletpheresis in donors at our blood bank.

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## MATERIAL AND METHODS

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This prospective study was conducted in our department for a period of one year from July 2012 to July 2013. First-time healthy plateletpheresis donors were enrolled for SDP during this period. All the donors were selected according to the guidelines laid down by Drugs and Cosmetics Act, 1940<sup>10</sup> and American Association of Blood Bank.<sup>11</sup> According to our departmental standard operating procedure, criteria for eligibility for plateletpheresis were as follows: (i) age 18-60 years; (ii) pre-apheresis platelet count greater than or equal to  $200 \times 10^9/L$ ; (iii) haemoglobin levels greater than or equal to 12.5 g/dL; (iv) donor body weight greater than or equal to 65 kg; (v) non-reactive test results for human immunodeficiency virus (HIV) 1, 2 antibodies and p-24 antigen; hepatitis B surface antigen, hepatitis C antibody, malaria and syphilis; (vi) absence of any illness; (vii) time lapse of at least 3 months since last whole blood donation; (viii) time lapse of at least 3 days since last plateletpheresis; and (ix) no consumption of non-steroidal anti-inflammatory drugs and acetyl salicylic acid in the last 7 days who were

in good health, were feeling well and had adequate venous access. Details of plateletpheresis procedure were explained to each donor and the consent was obtained before the procedure. All donations were performed using Fresenius Kabi COM.TEC apheresis machine (Fresenius Kabi AG, Bad Homburg, Germany). Haematological parameters of the donors were analysed using calibrated automated analyser (BC-5300 Auto Hematology Analyser, Shenzhen Mindray; Biomedical Electronics Co. Ltd, China). Blood flow rate for all collections was maintained at 50-60 mL/min with anticoagulant to blood ratio of 1:12. The endpoint was 300 mL of SDP with the target yield of  $3 \times 10^{11}$  platelets per unit. Two mL of whole blood from the donor was collected into ethylene diamine tetra acetic acid bottles just before and within 30 minutes after the procedures. Pre- and post-plateletpheresis haematological values, such as, haemoglobin, haematocrit, platelet count, mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentration (MCHC), PDW, RBC count and WBC count were analysed.

## Statistical analysis

Data are presented as mean  $\pm$  standard deviation. The mean pre- and post-plateletpheresis values were compared using paired t-test. Statistical analysis was carried out using statistical software SPSS version 16. A p-value less than 0.05 was considered significant.

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## RESULTS

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During the study period, 90 plateletpheresis donors were studied. Their mean age was  $28 \pm 6.61$  (range 19-45) years; all were males. Eight donors (8.9%) were in the age group of 18-20 years; 55 donors (61.1%) were in 21-30 years age group; 19 donors (21.1%) were in 31-40 years age group; and 8 donors (8.9%) were in 41-50 years age group. Blood group distribution in them was as followed: O Positive (n=48; 53.3%) B Positive (n=21; 23.3%), A Positive (n=12; 13.3%), AB Positive (n=5; 5.5%), B

**Table 1: Pre-and post-plateletpheresis haematological values**

Parameter	Pre- donation		Post- donation		p-value
	Mean±SD	Range	Mean±SD	Range	
Hb (g/dl)	14.8±1.097	12.6-17.3	14.5±1.4	10.6-17.3	0.002
Hct (%)	43.29±6.62	36.6-98.3	41.64±4.96	30.1-68.5	0.045
Plt (x10 <sup>9</sup> /L)	280.34±54.55	208-589	175.58±44.56	100-295	<0.001
MCV (fL)	84.21±5.16	68-108	83.99±5.12	67.4-106.1	0.213
MPV (fL)	8.61±0.77	6.8-10.9	8.72±0.83	6.8-12.0	0.067
PDW (fL)	15.96±1.38	3.3-16.8	16.27±0.39	15.1-17.8	0.039
RBC (million/μL)	5.08±0.41	4.12-6.03	4.96±0.67	2.28-8.01	0.053
WBC (×10 <sup>3</sup> /μL)	8.28±1.88	4.6-14	6.95±1.76	2.02-11.13	<0.001

Hb = haemoglobin; Hct = haematocrit; Plt = platelet count; MCV = mean corpuscular volume; MPV = mean platelet volume; PDW = platelet distribution width

Negative (n=2; 2.2%) and O Negative (n=2; 2.2%). The mean pre-donation haemoglobin was 14.8 ± 1.1 g/dL (range 12.6-17.3). The mean pre-donation platelet count was 280.3 ± 54.6 ×10<sup>9</sup>/L (range 208-589). Following plateletpheresis, the haemoglobin concentration (p=0.002), haematocrit (p=0.045), and PDW (p=0.039) significantly decreased in the donors (Table 1). There was also a significant decrease in post-donation platelet count (p<0.001) and WBC count (p<0.001). A decrease in MCV (p=0.213) and RBC count (p=0.053) was observed after plateletpheresis but this was not statistically significant. However, we observed a slight but statistically insignificant rise in post-donation MPV in our donors (p=0.067). Four donors (4.4%) had a post-plateletpheresis haemoglobin level of less than 12 g/dL but no untoward clinical event occurred either during or after the procedure. Out of these four donors, three had a pre-donation haemoglobin levels greater than 13 g/dL and one had a pre-plateletpheresis haemoglobin level of 12.7 g/dL.

We observed two donors (2.2%) to have a post-procedure platelet count of less than 100×10<sup>9</sup>/L; associated clinical manifestations were not evident.

Two of our donors had donated twice at an interval of 5 weeks. But there were no significant decrease in haematological parameters before or after the second donation.

## DISCUSSION

Developments in medical sciences, including organ transplantation programs, has significantly increased the demand for platelets.<sup>12</sup> Collection of platelets by apheresis has been a major advance in transfusion medicine and it is advantageous over random donor platelets. Such SDPs allow supply of a therapeutically beneficial component ensuring leucocyte reduction of less than 5 × 10<sup>6</sup>/unit thereby decreasing febrile non-haemolytic transfusion reactions, limited donor exposure thereby reduced infectious complications and supply of HLA matched platelet concentrates in refractory patients.<sup>13,14</sup> During the last decades there have been significant improvements in the productivity and quality of apheresis platelets. Today, more emphasis is placed on introducing new generation machines that can guarantee consistent product quality with optimum leukoreduction. Although such collections from eligible donors have optimized the availability of platelet and their transfusions and, blood centres are also emphasizing on donor safety in parallel to product quality while performing these procedures. However, donor safety issues in plateletpheresis have, received relatively little attention. In our present study, donor safety issues with regards to reductions in haematological values after plateletpheresis

were addressed. In our study, a significant reduction in platelet and WBC count was observed post-plateletpheresis. In another study<sup>15</sup> evaluating the effect of various cell separators on donor haematological parameters reported that platelet count and WBC count decreased significantly when Fresenius COM.TEC cell separator was used. So the highly significant decrease platelet count and WBC count reported in our study could be because of the use of the Fresenius COM.TEC cell separator. Our data showed that after the procedure, values for haemoglobin ( $p=0.002$ ), haematocrit ( $p=0.045$ ), and PDW ( $p=0.039$ ) decreased significantly in the donors. Similar results were reported in other studies.<sup>16,17</sup> However, in another study,<sup>18</sup> a decrease in Hb, Hct and WBC count and an increase in platelet count were observed post-plateletpheresis. The decrease in values in our study could be as a result of infusions of anticoagulant solutions and 0.9% normal saline during the procedure<sup>19</sup> or it could be due to blood loss in the residual volume of apheresis kit. We observed a decrease in MCV and RBC, but these changes were not clinically significant. We observed a slight increase in MPV which has also been reported in another study.<sup>15</sup> In our study 2.2% of donors had a decrease in platelet count less than  $100 \times 10^9/L$  post-procedure without any associated clinical manifestations. In another study<sup>20</sup> also a similar post-procedure decline in platelet count to less than  $100 \times 10^9/L$  had been reported in 2.1% of donors. Some workers<sup>15</sup> have reported that decrease in platelet count could be a concern for clinical thrombocytopenia in donors who have a predonation platelet count of less than  $200 \times 10^9/L$ . But in our study, none of the donors had a pre-donation platelet count of less than  $200 \times 10^9/L$ . This is because, according to our departmental standard operating procedure, only those donors who have a platelet count of  $200 \times 10^9/L$  or above were taken up for donation. It has been recommended that donors

who have a low or borderline pre-donation platelet count and haemoglobin levels should be assessed and monitored post-donation for decrements in haematological parameters.<sup>21</sup> A significant and sustained decrease in platelet count for all donation frequency categories has been documented in an earlier report but none of the donors had clinical thrombocytopenia.<sup>22</sup> Moreover, the relative safety and efficacy of repeat plateletpheresis procedures when a single donor was committed to a maintenance regime for a designated patient has been reported.<sup>23</sup> It has also been observed that even triple plateletpheresis procedure does not result in either short-term post-apheresis thrombocytopenia or long-term donor platelet depletion also and it was independent of the type of apheresis machine used.<sup>9</sup> Though the mean platelet count decreased significantly post-plateletpheresis in our study, there were no clinical symptoms like prolonged bleeding from the phlebotomy site, petechiae or purpura. Further, the post-donation platelet count did not decrease below  $100 \times 10^9/L$ . It has been reported that plateletpheresis was associated with statistically but not clinically important decrease in platelet count in another study.<sup>24</sup>

Under a situation of limited human resources and shrinking donor population, both platelet availability and donor safety should go hand in hand. In our study, donor safety was ensured throughout the procedure. Though a significant decrease in the post-procedure haematological values were evident the donors, no significant clinical manifestations were evident. We recommend that haematological parameters have to be tested following the procedure in plateletpheresis donors. This will be of value in establishing post-donation reference ranges which could be utilized when reviewing the suitability of donors for subsequent donations thereby ensuring both donor safety and product quality. Further studies on close monitoring and follow-up of these donors are needed in order to look for any long-term consequences.

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