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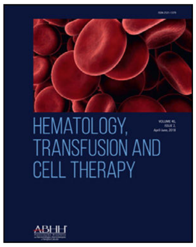

Original article

Effect of double dose plateletpheresis on target yield and donor platelet recovery

Sapna Chopra [a], *Paramjit Kaur* [b,*], *Ravneet Kaur Bedi* [b], *Gagandeep Kaur* [b]

[a] *All India Institute of Medical Sciences, Ansari Nagar, New Delhi, India*
[b] *Government Medical College and Hospital, Sector 32, Chandigarh, India*

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ABSTRACT

Introduction: The demand for apheresis platelets has increased in the recent past and the shrinking donor pool has shifted the trend to collection of double-dose or higher yield of platelets.
Objective: The present study aimed to determine the effect of double-dose plateletpheresis on the target yield and donor platelet recovery.
Methods: The study was conducted on 100 healthy plateletpheresis donors, 50 of whom were in the study group, which underwent double-dose plateletpheresis (DDP), and 50 of whom were in the control group for single-donor plateletpheresis. Pre- and post-procedure samples of donors were subjected to a complete blood count. The DDP product was sampled for platelet yield and then split into two parts. Platelet yield, collection efficiency, collection rate, recruitment factor and donor platelet loss were calculated.
Results: The mean platelet yield in the SDP was $4.09 \pm 1.15 \times 10^{11}$ and in the DDP, $5.93 \pm 1.04 \times 10^{11}$. There was a significant correlation between the pre-donation platelet count and platelet yield. The total of platelets processed for the SDP were $5.42 \pm 1.08 \times 10^{11}$ and for the DDP, $7.94 \pm 0.77 \times 10^{11}$. The collection efficiency was $71.93 \pm 25.14\%$ in the SDP and $72.94 \pm 16.28\%$ in the DDP, while the collection rates were 0.78×10^{11} and 0.94×10^{11} per minute, respectively. The average recruitment factor observed was 0.98 in the SDP, while it was 0.99 in the DDP. The mean platelet loss observed in the SDP was $35.55 \pm 8.53\%$ and in the DDP, $37.76 \pm 8.65\%$.
Conclusion: The double-dose plateletpheresis supplements the platelet inventory in developing countries where the apheresis donor pool is limited. It is prudent to ensure stringent donor selection criteria for donors donating high-yield platelet products, thus enhancing donor safety and retention.

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[*] **Corresponding Author at:** Department of Transfusion Medicine, Government Medical College and Hospital, Sector 32-B, Chandigarh, India, Postal code 160030, Phone: 91 172 2601023. Ext 2210.
E-mail address: paramjit.gp71@yahoo.com (P. Kaur).

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Introduction

Plateletpheresis is the procedure of collecting platelets from the donors using automated apheresis machines known as single donor platelets (SDPs). With the advent of newer techniques of component extraction and newer generation apheresis platforms with better efficiency for platelet collection, it is now considered as an integral part of modern transfusion practice.[1] The increasing trend in platelet demand due to the rising number of patients with various bleeding manifestations and also developments in medical sciences, including transplantation programs, has significantly escalated the demand for platelets (PLTs).[2,3] Due to availability of SDPs, the treatment of patients with oncological and hematological disease and bone marrow transplantation has improved, as it provides an efficient means of platelet support from a single donor, minimizing platelet transfusion refractoriness.[4] Apart from the greater dose, SDPs are leukodepleted, which further helps in the prevention of transfusion reactions, such as the febrile nonhemolytic transfusion reaction (FNHTR), human leukocyte antigen (HLA) alloimmunization and transmission of infectious agents, which are more associated with random donor platelets (RDP).[5]

Storage of platelets at room temperature poses a risk for bacterial contamination. The shelf life of platelets is limited to five days and the selection of plateletpheresis donors is based on stringent eligibility criteria, which is crucial in maintaining an adequate platelet inventory. Due to the shrinking donor pool and increasing demand for single donor platelets, the practice of collecting a double dose of platelets or even higher yield is on the rise. This is possible due to the newer generation apheresis platforms with better efficiency for platelet collection. This further helps in reducing the cost, risk of multiple donor exposure and adverse transfusion reactions associated with allogeneic transfusion.[6]

The standards prescribed by the American Association of Blood Banks (AABB) mandates that SDPs should have at least 3.0×10^{11} platelets in each unit. With modern mechanical blood cell separators, the collection of the double dose and triple dose of platelets from a single donor is feasible, but each unit collected from these must meet the quality control criteria, as per prescribed standards.[7] Donor safety is of prime importance in plateletpheresis donors to avoid high platelet loss and prevent adverse donor reactions, but there is a paucity of data for the same in the acquisition of higher yield products. The present study aimed to analyze the effect of double-dose platelet (DDP) extraction on platelet product quality and donor platelet recovery.

Materials and methods

The current study was a prospective observational study conducted in the Department of Transfusion Medicine of a tertiary care center. The study was undertaken after receiving the approval of the Institutional Research and Ethics Committee. Informed written consent was obtained from all the donors.

A total of 100 healthy plateletpheresis donors (both voluntary and replacement) eligible for donation and willing to participate in the study were included. The subjects were divided into two groups:

Study group: Donors fulfilling criteria for DDP collection ($n = 50$).

Control group: Donors eligible for SDP collection ($n = 50$).

All donors (first time or repeat) meeting the general eligibility criteria for plateletpheresis established by the Drug Controller General of India and the Director of General Health Services (DGHS) guidelines were considered for enrolment in the study.[8,9] In addition, donor selection for DDP extraction was based on additional criteria, such as weight ≥ 60 kg, Hemoglobin (Hb) ≥ 13.0 g/dL, platelet count $\geq 250 \times 10^9$/L, previous plateletpheresis more than one month beforehand or whole blood donation more than 3 months previously. The platelet count cutoff for the control group (SDP) was $\geq 150 \times 10^9$/L. A pre-donation sample from each donor was subjected to a complete blood count (CBC) using automated cell counter (Cell Tech Automated Cell Counter, Rome, Italy), blood grouping by tube method and screening for transfusion transmitted infection (TTI) markers anti-HIV 1 and 2, anti-HCV, HBsAg, syphilis and malaria, as per departmental standard operating procedure.

The plateletpheresis procedure was performed on the Amicus cell separator (version 2.5) using single-needle closed-system apheresis kits for both SDP and DDP collection. The anticoagulant acid citrate dextrose (ACD) infusion rate was 1.25 mg/kg/min, the maximum inlet rate varied from 45 ml/min to 150 ml/min. The endpoint was the target yield set. The target yield for each procedure in the study group was $\geq 6.0 \times 10^{11}$ and in the control group, between 3×10^{11} and 4×10^{11}. The collection time, processed blood volume, ACD used, product volume, post platelet count, post hematocrit (Hct) and total saline used was recorded at the end of each procedure.

After the completion of the procedure, the donor rested for 15–20 min and a 2 ml post-donation sample of the donor was collected in an EDTA vial and subjected to a complete hemogram. The platelet product was rested for one hour for proper disaggregation before sampling. The sample was taken from the primary bag and tested for platelet content. The final product of the study group was then split into two equal parts using a weighing scale and labelled as A and B and, as described above, representative samples were taken from each bag and subjected to platelet count and leucocyte count on an automated hematology analyzer. The sample was collected after ensuring thorough stripping of the attached segment. The final volume of each bag, both A and B, was also recorded (Figure 1).

Calculation of procedure parameters[10–12]

Platelet yield was determined by:

Product volume (mL) × product count (platelets/μL) × conversion factor (1000μL/mL)

Platelet collection efficiency (CE) was calculated by:

Platelet yield / Total platelets processed × 100

Total platelet processed = (pre- + post-count platelets/μl)/2 × total blood volume processed (ml) × conversion factor (1000 μl/mL)

Total blood volume processed = Blood volume processed (ml) - anticoagulant (ml)

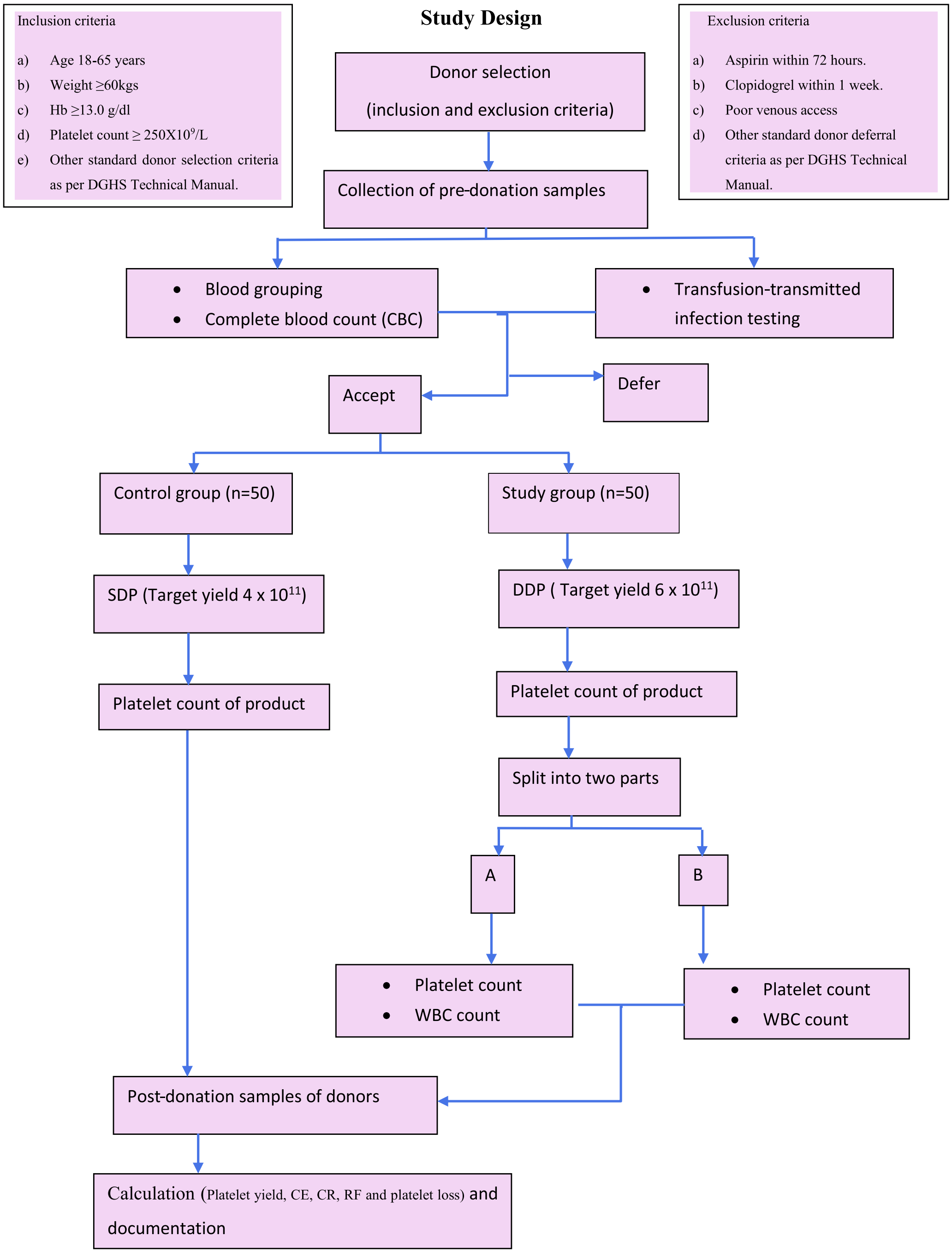
Study Design
Inclusion criteria
a) Age 18-65 years
b) Weight ≥60kgs
c) Hb ≥13.0 g/dl
d) Platelet count ≥ 250X10⁹/L
e) Other standard donor selection criteria as per DGHS Technical Manual.
Donor selection (inclusion and exclusion criteria)
Exclusion criteria
a) Aspirin within 72 hours.
b) Clopidogrel within 1 week.
c) Poor venous access
d) Other standard donor deferral criteria as per DGHS Technical Manual.
Collection of pre-donation samples
Blood grouping
Complete blood count (CBC)
Transfusion-transmitted infection testing
Accept
Defer
Control group (n=50)
Study group (n=50)
SDP (Target yield 4 x 10¹¹)
DDP (Target yield 6 x 10¹¹)
Platelet count of product
Platelet count of product
Split into two parts
A
B
Platelet count
WBC count
Platelet count
WBC count
Post-donation samples of donors
Calculation (Platelet yield, CE, CR, RF and platelet loss) and documentation

Figure 1 – Flow-chart showing operational flow for plateletpheresis.

Collection Rate (CR) calculated as Yield/procedure time (CR/min)
Recruitment factor (RF) calculated by the formula (Post-donation cell count + yield)/Pre-donation cell count
Platelet loss was derived by Pre-platelet count in whole blood - post donation count/Pre-platelet count in whole blood × 100

Statistical analysis

The statistical analysis was performed using the Statistical Package for the Social Sciences (SPSSInc, Chicago, IL, Version 22.0 for Windows). All quantitative variables were estimated using measures of central location (mean) measures of dispersion (standard deviation). Qualitative or categorical variables are described as frequency and proportions. To verify the relationship between two variables, the Spearman or Pearson correlation coefficient was calculated. All the statistics were two-sided, performed at a significance level of $\alpha = 0.05$. A p-value of < 0.05 was considered significant.

Results

During the study period, a total of 108 donors were found eligible for plateletpheresis, out of which 8 were excluded from

Table 1 – Donor baseline parameters.

Parameters	Control Group	Study Group	Range
Age (years)	29.24 ± 6.78	28.70 ± 5.96	19–50
Height (cm)	174.70 ± 4.6	175.24 ± 4.20	168–185
Weight (kg)	75.9 ± 10.70	77.58 ± 12.71	52–107
Hemoglobin (g/dL)	15.34 ± 1.12	15.002 ± 1.35	12.5–17.6
Hematocrit (%)	44.15 ± 4.25	43.96 ± 3.47	35.85–59.80
Platelet count (x 10^9/L)	238.6 ± 35.4	300.4 ± 42.3	182–250
MPV (fL)	10.15 ± 1.79	10.03 ± 1.03	8–12.9
PDW	36.9 ± 2.6	36.9 ± 2.2	30.5–34.8

the study, as consent was not given. Among the 100 donors, 64 were found fit for DDP extraction, but 14 donors were not willing to undergo this procedure, hence, 50 donors were included in the study group, having a platelet count > 250 × 10^9/L, and the remaining 50 were included in control group, with a platelet count > 150 × 10^9/L. All the donors were males, out of which 71% were replacement donors and the rest (29%) were voluntary donors. The mean age was 29.24 ± 6.78 years in the control group and 28.70 ± 5.96 years in the study group. Donor baseline characteristics are shown in Table 1. Out of 100 donors, 37 donors had platelet count between 251 and 300 × 10^9/L, of which 9 (18%) were in the control group and 28 (56%) were in the study group. In the control group, 31 donors had a platelet count of 201 to 250 × 10^9/L, while in the study group, 43 donors had a platelet count between 251 and 350 × 10^9/L. Only 4 donors in the study group had a platelet count above 351 × 10^9/L.

The mean pre-donation hemoglobin of donors was 15.34 ± 1.12 g/dL in the control group and 15.00 ± 1.35 g/dL in the study group while the post-donation hemoglobin was 15.12 ± 1.85 g/dL in the control group and 15.02 ± 1.33 g/dL in the test group. The difference was statistically insignificant ($p > 0.05$). Concerning the hematocrit, there was a decrease of 1.09 (2.48%) in the control group and 0.61 (1.40%) in the study group, which was statistically significant ($p < 0.05$). The mean pre-donation platelet count of donors was 238.56 ± 35.42 × 10^9/L (Range 182 – 326 × 10^9/L) in the control group and 300.40 ± 1.79 × 10^9/L (Range 248–450 × 10^9/L) in the study group, while the post donation platelet count was 149.69 ± 45.91 × 10^9/L (Range 86–222 × 10^9/L) in the control group and 185.34 ± 35.17 × 10^9/L (Range 112 – 263 × 10^9/L) in the test group. The mean decline in the control group was 88.87 × 10^9/L (37.25%) and in the study group, 115.06 × 10^9/L (41.63%). The difference in the post-procedure decline in the donor platelet count was statistically significant between the study and control groups ($p = 0.000$).

A Wilcoxon signed-rank test revealed a statistically significant decline in the post- and pre-hematocrit (Z = −2.602; $p = 0.000$), platelet count (Z = −6.155; $p = 0.000$), mean platelet volume and platelet distribution width (PDW) in the control group. In the study group, the difference was significant for the platelet count ($p = 0.000$), mean platelet volume ($p = 0.038$) and PDW ($p = 0.001$) (Table 2).

The levels of all machine- and procedure-related variables were assessed during and after the procedure. The mean post platelet count of donors calculated by machine was 158.28 ± 37.068 × 10^9/L in the control group and 189.80 ± 33.300 × 10^9/L in the study group, while the mean post-hematocrit

Table 2 – Wilcoxon signed-rank study for hematological parameters in both groups.

Group		Hb(g/dl) – Post-procedure - Hb(g/dl) – Pre- procedure	Hct(%) – Post-procedure - Hct(%) – Pre- procedure	Plt(10^9/l) – Post-procedure - Plt (10^9/l) – Pre- procedure	MPV(fl) – Post-procedure - MPV(fl) – Pre- procedure	PDW – Post- procedure - PDW – Pre- procedure
Control Group	Z	−0.378[a]	−2.602[a]	−6.155[a]	−4.299[a]	−4.118[a]
	Asymp. Sig. (2-tailed)	0.705	0.009	0.000	0.000	0.000
Study Group	Z	−0.648[b]	−1.752[a]	−6.155[a]	−2.072[a]	−3.371[a]
	Asymp. Sig. (2-tailed)	0.517	0.080	0.000	0.038	0.001

[a] Based on positive ranks.
[b] Based on negative ranks.

Table 3 – Effect of plateletpheresis on machine-related parameters.

Parameter	Group	Mean	SD	Range	P-value
Post PLT (x 10^9/L)	Control Group	158.28	37.068	108–227	0.000
	Study Group	189.80	33.300	146–305	
Post-Hct (%)	Control Group	40.57	4.370	31–53	0.994
	Study Group	40.57	3.480	34–47	
ACD used (mL)	Control Group	365.09	73.552	264–470	0.000
	Study Group	443.78	52.430	304–549	
WBP (mL)	Control Group	3129.08	535.744	2050–4325	0.000
	Study Group	3762.58	464.488	2411–4704	
Time (min)	Control Group	68.92	13.844	43–106	0.000
	Study Group	79.52	11.977	56–110	
Flow rate (mL/min)	Control Group	90.90	7.867	74–110	0.014
	Study Group	94.74	7.420	76–100	

calculated by machine was 40.57 ± 4.37% in the control group and 40.57 ± 3.480% in the test group. The post-platelet count difference was statistically significant ($p = 0.000$) between the two groups (Table 3).

The platelet yield achieved for the control group against a target yield of 4×10^{11} was $4.09 \pm 1.15 \times 10^{11}$, whereas in the study group, in which the target yield was 6×10^{11}, the mean yield achieved was $5.93 \pm 1.04 \times 10^{11}$ ($p = 0.000$). It was also observed that in the control group there was a positive correlation between the hemoglobin, hematocrit and PDW of the donor with the platelet yield. However, in the study group, the hemoglobin, hematocrit and platelet count showed a positive correlation with the platelet yield. For the pre-donation platelet count, there was a statistically significant ($r = 0.267$; $p = 0.000$) positive correlation in the study group (Figure 2).

The procedure parameters are summarized in Table 4. In both the study and control groups, volumes of product, total platelets processed and collection rates were positively correlated with the product yields. A similar positive correlation was observed for the collection efficacy (Figure 3) and recruitment factor with the product yield. The platelet loss showed a positive correlation with the yield in the control group, whereas it showed a negative correlation in the study group. In the control group, the recruitment factor was 0.97 ± 0.11, while in study group, the recruitment factor was 0.99 ± 0.16, ranging between 0.67 and 1.51. There was a negative correlation between the donor baseline platelet count and recruitment factor (Figure 4).

None of the donors in the control group presented adverse reactions, while 3 donors in the study group experienced adverse reactions during the procedure. Two were citrate reactions in the form of paraesthesia, tingling and perioral numbness. One donor developed local reactions in the form of hematoma.

Discussion

Plateletpheresis has proven to be a boon in the field of Transfusion Medicine, as it provides a therapeutically beneficial component and ensures reduced donor exposure.[13] Technological advancements have made it possible to collect double, and even triple, doses of platelets amid a shrinking donor population. The platelet concentrates prepared with the help of automated cell separators are of high quality. However, plateletpheresis also has its impact on donor hematological

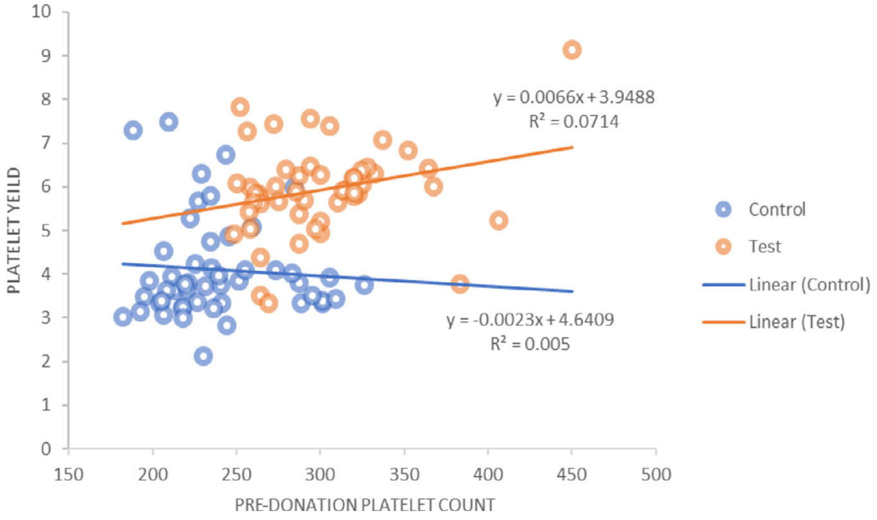

Figure 2 – Correlation between pre -donation platelet count of donor and platelet yield.

Table 4 – Procedure parameters in both groups.

Parameters	Group	Mean	Std. Deviation	P-value	Range
Vol. (ml)	Control Group	308.28	81.19	0.000	198–552
	Study Group	422.74	63.91		341–714
Platelet yield (x 10^{11})	Control Group	4.09	1.14	0.000	2.14–7.50
	Study Group	5.92	1.04		3.35–9.16
Total platelets processed (x 10^{11})	Control Group	5.42	1.08	0.000	3.77–9.87
	Study Group	7.94	0.77		5.38–9.55
Collection Efficiency (%)	Control Group	71.93	25.14	0.97	42–148
	Study Group	72.06	16.28		42–108
Collection Rate (10^{11}/min)	Control Group	0.07	0.12	0.53	0.027–0.93
	Study Group	0.093	0.13		0.033–1.00
Recruitment Factor	Control Group	0.9753	0.10	0.39	0.770–1.32
	Study Group	0.9984	0.15		0.670–1.51
Platelet loss (%)	Control Group	35.55	8.53	0.2	1–58
	Study Group	37.76	8.65		15–64

parameters and, with the increasing use of high yield plateletpheresis procedures, donor safety is an area of concern.

Donors included in our study were predominantly males, as in most studies, which also observed that women were associated with complications related to the venepuncture and were at increased risk of vasovagal reactions and adverse events, compared to males.[14–16] Tomita et al. found the incidence of vasovagal reactions among female apheresis donors to be 1.25%, while the rate among male donors was 0.83%.[17] Studies conducted by some authors considered the body weight for the platelet yield. Donors with weight below 65 kg had a lower platelet yield when DDP collection was performed.[18] However, in our study, we did not find any such correlation between weight and height of donors and platelet yield. Another study from India also did not find any significant effect of donor age, weight and height on platelet yield.[19]

We used a continuous type of cell separator in our study for plateletpheresis donation that is the Amicus, which has an extracorporeal volume of 210 ml. The amount of anticoagulant (ACD) transfused to donors used was 365.09 ± 73.552 ml in the control group, while in the study group it was 443.78 ± 52.430 ml. The mean whole blood volume processed and total time taken were higher in the study group, as expected. In a study to evaluate the Amicus separator in the collection of apheresis, the authors found that the Amicus efficiently collected single, as well as double, apheresis with a mean platelet yield of 4.2×10^{11} and 6.5×10^{11}, respectively. All apheresis performed were leukoreduced below 5.0×10^{6}, while one was below 1.0×10^{6}.[20]

Fontana et al. reported a PLT yield of 6.06×10^{11} in double yield collection using the Amicus.[21] Similar results were found by Keklik et al.,[22] while higher yield of $7.24 \pm 0.53 \times 10^{11}$ has been reported by other authors.[23] The DDP yield in our study of $5.93 \pm 1.04 \times 10^{11}$ was comparable to that of another study from India[24] but was lower, when compared to studies by other authors.[21–23] This could be due to differences in pre-procedure platelet count and target yield in various studies.

Positive correlation between the hemoglobin, hematocrit and pre-donation platelet count of donor and platelet yield was seen in the study group. For the pre-donation platelet count, there was a statistically significant positive correlation in the study group. In the control group, the hemoglobin showed a positive correlation with the platelet yield. The

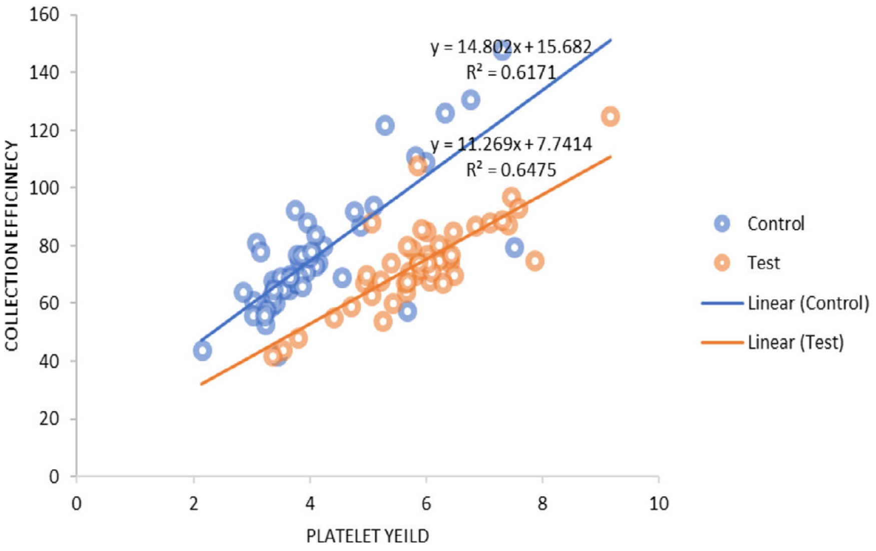

Figure 3 – Correlation between platelet yield and collection efficiency.

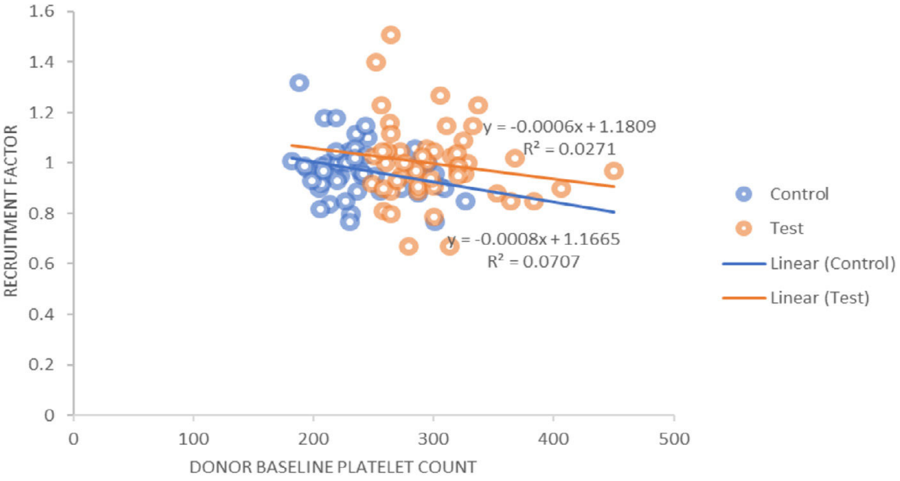

Figure 4 – Correlation between donor baseline platelet count and recruitment factor.

platelet count showed a slight negative correlation in the control group, with respect to the platelet yield. This could be due to procedure-related problems, such as the low flow rate observed in some procedures. Another study also showed a positive correlation between the donor pre-donation platelet count and the platelet yield in DDP and suggested that the donor platelet count is an important determinant for the yield and that a count below $225 \times 10^3/\mu L$ is not suitable for DDP collection.[18] Authors have suggested that DDP collection may be performed when the donor platelet count is above $250 \times 10^3/\mu L$.[25]

The relation between the donor baseline platelet count and the yield was analyzed. Out of 50 donors in the study group, 19 had a platelet count in the range of 250 to $280 \times 10^9/L$ and the mean yield was $5.696 \pm 1.57 \times 10^{11}$ in the product obtained from these donors, while 9 donors had a yield less than 5×10^{11}. For 11 donors with a platelet count ranging between 280 and $300 \times 10^9/L$, the mean yield was $6.07 \pm 0.96 \times 10^{11}$ and with counts greater than $300 \times 10^9/L$, the mean yield was $6.14 \pm 0.99 \times 10^{11}$. The higher the platelet count, the more platelets are available for collection. In our population, donors with a baseline platelet count $\geq 280 \times 10^9/L$ are more likely to donate double-yield platelet products.

Guerrero-Rivera et al.[26] and Enein et al.[27] also observed that the pre-donation platelet count was directly proportional to the platelet yield, while an inverse relationship was observed with donor hemoglobin and platelet yield.[26] They also observed a significant reduction in the hemoglobin, hematocrit, leucocyte and platelet count of the donor after the procedure.[27] Authors from India have also demonstrated the direct relationship between the pre-donation platelet count and platelet yield.[12,19] They also suggested that, in the Indian scenario, it would be more relevant to follow the European guidelines of a platelet yield $> 2 \times 10^{11}$ platelets per unit.[19]

On correlation of machine parameters with the platelet yield, we observed that the ACD used and the apheresis derived platelets showed a positive correlation in the control group and a negative correlation in the study group. The total time taken was negatively correlated in both groups, while flow rate showed a positive correlation. All these parameters were statistically significant between the two groups. Enein et al. analyzed the impact of various donor- and machine-related parameters on the platelet yield in 127 procedures. They found that the anticoagulant infusion rate, total blood volume processed and time taken had a positive impact on the platelet yield.[27] Beyan et al. found that factors, such as the maximum draw rate, maximum return rate, whole blood processed, processing time and pre-procedure platelet count could have a significant effect on the yield in plateletpheresis.[28]

We also observed a decrease in donor hemoglobin in the control group and a mild increase in the study group. The hematocrit showed a decline in both groups which was significant. The increase in the donor Hb in the study group may be because red cells are transfused back to the donor and 300 to 400 ml of plasma is retained at the end of the procedure. Due to this, there is a hemoconcentration in the donor. Tendulkar et al.[29] and Das and workers[30] found a statistically significant decline in the donor Hb, Hct and platelet count post-procedure, without any clinical evidence of anemia and thrombocytopenia.

The change in the donor platelet count after donation was also analyzed. The decline in the donor platelet counts observed in the control and study groups were 37.25% and 41.63%, respectively, and the difference was statistically significant. A decrease in the mean platelet volume (MPV) and PDW was observed in both groups. Strasser et al.[11] reported a platelet count decrease of $27.1 \times 10^3/\mu l$ (7.7%) post-donation using the machine AS TEC 204, while a decrease of $26 \times 10^3/\mu l$ (12.9%) was reported with the COBE spectra. A higher decline in our study could be attributed to the timing of the post-donation sample and a different cell separator. Das et al., using five different cell separators, observed that there was no significant change in donor MPV or PDW after each procedure in 457 plateletpheresis procedures.[30]

The total platelet volumes processed in our study were $5.42 \pm 1.08 \times 10$ and $7.95 \pm 0.77 \times 10^{11}$ ($p = 0.000$) in the control and study groups, respectively. The collection efficiency observed in our study was $71.93 \pm 25.14\%$ in the control group and 72.07 ± 16.28% in the study group. Makroo et al.[12] reported the CE to be 78.09%, while the CE observed by Chaudhary et al.[24] was 59.7% and, in the study by Jaipian et al.,[23] 85.31%, for DDP collection using the Amicus. In a study conducted on the Trima Accel cell separator, the authors reported efficient DDP collection with a median PLT yield of 3.7×10^{11}, mean CE of 74.99 ± 14.40% and mean CR of $0.096 \pm 0.012 \times 10^{11}$/min.[31] The collection rate found in our study was $0.78 \pm 0.12 \times 10^{11}$/min. and $0.94 \pm 0.13 \times 10^{11}$/min. in the control and study groups, respectively.

The recruitment factor was 0.97 ± 0.11 in the control group, while in the DDP group the recruitment factor was 0.99 ± 0.16, ranging between 0.67 and 1.5 ($p = 0.313$). We also observed the platelet loss of 35.55 ± 8.53% in the control group, while in the study group it was 37.76 ± 8.65 ($p = 0.200$). Fontana et al.[21] found that the PLT recruitment (1.56 ± 0.31) caused a higher post-PLT count than that predicted by the instrument ($p < 0.0001$).

In both groups, the product volume, total platelets processed, collection rate, collection efficacy and recruitment factor were found to be positively correlated with the product yield. The platelet loss was positively correlated with the yield in the control group, while it was negatively correlated in the study group. The product volume and total platelet product were found to be statistically significant ($p = 0.000$). Strasser et al. found a negative correlation between the baseline platelet count and recruitment factor ($r = -0.38$; $p = 0.003$), while there was a positive correlation between the platelet yield and recruitment factor ($r = 0.44$; $p = 0.001$), as well as between the collection efficacy and recruitment factor ($r = 0.025$; $p = 0.05$). They also studied the correlation of different variables which could affect the platelet yield and collection efficacy and found a strong negative correlation between the platelet baseline counts and RF ($r = -0.662$; $p < 0.001$).[11]

Plateletpheresis procedures are well tolerated, but sometimes donors may experience adverse reactions that can be localized or systemic. In our study, out of a total of 100 donors, no donors in the control group showed any adverse reactions, while 2 donors in the study group experienced citrate reactions, which were corrected by oral calcium supplementation, and one had a local reaction. Chaudhary et al.[24] found adverse effects in 22.4% of their donors who underwent DDP collection. In a recent retrospective study, the adverse reaction rates were reported at 10.34% in high-yield procedures and 5.68% in normal-yield procedures. The authors reported 3.23% of phlebotomy-related complications and 2.28% of reactions due to citrate toxicity.[32]

We also assessed the quality of apheresis platelet concentrates. Swirling was present in 93% of the units. The platelet count was over 3×10^{11} in all fifty units in the control group and over 6×10^{11} in twenty-three units in the study group. The individual yield in split products in the study group was $2.74 \pm 0.55 \times 10^{11}$. The authors reported that the fresh PCs have swirling in 83% of the units, which was reduced to 65% after 5 days of storage. They attributed this decline to storage lesions that are known to occur after platelet preservation.[33] The AABB requires that 95% of the units tested have a leucocyte count $\leq 5 \times 10^6$. In our study, the average leucocyte count in products from the control group was $2.88 \pm 0.2 \times 10^6$ and in the study group, $1.64 \pm 0.5 \times 10^6$; hence, all products were leukoreduced.

There were certain limitations in our study. All donors included in the study were males, so the effect of plateletpheresis on female donors could not be studied. The donor sample was obtained soon after the completion of the procedure and hence, the change in hematological parameters observed may not be representative. It would have been desirable to have a daily hematological parameter post-donation assessment to determine the trend of the platelet recovery, but due to logistic problems and the convenience of the donors, this could not be performed. Although no significant adverse events were observed in donors undergoing DDP, the frequency of high-yield procedures and its effect on donor safety were not studied in our population due to the limited donor pool in this subset. However, we conducted a comprehensive analysis of data comparing single- and double-dose plateletpheresis which would encourage transfusion medicine specialists to employ double-dose platelet collection among eligible blood donors in developing countries, which will go a long way in reducing cost and, at the same time, the transfusion risks.

Conclusion

We conclude that double-dose or higher yield plateletpheresis can supplement limited platelet inventory and limit donor exposure, which can further be of immense importance in the setting of a developing country. Donors with lower MPV and PDW tend to donate products with a higher yield. Donors with a higher platelet count yield DDP products with higher yield. With improved automated platforms, procedure duration is shorter, even in high-yield products, thus enhancing donor comfort.

Ethical approval statement

The study was approved by the institutional ethics committee.

Donor consent statement

All donors who participated in the study gave written informed consent.

Conflicts of interest

The authors declare no conflicts of interest.

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REFERENCES

1. Apheresis: definitions, descriptions, and developments. Health Technology Case Study 23: The Safety, Efficacy, and Cost Effectiveness of Therapeutic Apheresis. Washington, D. C.: U.S. Congress, Office of Technology Assessment; 1983 OTA-HCS-23.
2. Krailadsiri P, Seghatchian J. Are all leukodepleted platelet concentrates equivalent? Vox Sang. 2000;78(3):171–5.
3. Zingsem J, Moog R. Preparative haemapheresis and donor safety. Transfus Med Hemother. 2004;31(1):5–6.
4. Slichter SJ. Platelet transfusion therapy. Hematol Oncol Clin N Am. 2007;21(4). 697-729.
5. Chambers AL, Kruskall SM, Pacini GD, Donovan ML. Febrile reactions after platelet transfusion: the effect of single versus multiple donors. Transfusion. 1990;30(3):219–21.
6. Kakaiya R, Aronson CA, Jullies J, Roback JD, Combs MR, Grossman BJ, Hillyer CD. Whole blood collection and component processing. Technical Manual American Associations of Blood Banks. 18th ed. AABB press; 2014.
7. Apheresis Platelets- US Guidance-ICCBBA 2015. Available from https://www.iccbba.org/docs/tech.
8. The Drug and Cosmetic Act and Rules. Ministry of Health & Family Welfare. Government of India; 2016.
9. Saran RK. Apheresis. In: Saran RK, ed. Transfusion Medicine Technical Manual. Director General of Health Services, 2nd ed., New Delhi: Ministry of Health and Family Welfare, Government of India; 2003:229–44. editor.
10. Fontana S, Keller P, Taleghani BM. Platelet recruitment during multiple donor platelet apheresis differs between cell separators. Transfus Med Hemother. 2011;38(3):195–8.
11. Strasser EF, Schuster M, Egler K, Bauer J, Weisbach V, Ringwald J, et al. Frequently used plateletpheresis techniques result in variable target yields and platelet recruitment of donors. Transfusion. 2005;45(5):788–97.
12. Makroo RN, Fadadu D, Agrawal S, Chowdhry M. Double dose plateletpheresis: A savior to shrinking donor pool and platelet inventory management. Indian J Hematol Blood Transfus. 2018;34(4):691–6.
13. Ness PM, Campbell-Lee SA. Single donor versus pooled random donor platelet concentrates. Curr Opin Hematol. 2001;8(6):392–6.
14. Winters JL. Complications of donor apheresis. J Clin Apher. 2006;21(2):132–41.
15. Philip J, Sarkar RS, Pathak A. Adverse events associated with apheresis procedures: incidence and relative frequency. Asian J Transfus Sci. 2013;7(1):37–41.
16. Despotis GJ, Goodnough LT, Dynis M, Baorto D, Spitznagel E. Adverse events in platelet apheresis donors: a multivariate analysis in a hospital-based program. Vox Sang. 1999;77(1):24–32.
17. Tomita T, Takayanagi M, Kiwada K, Mieda A, Takahashi C, Hata T. Vasovagal reactions in apheresis donors. Transfusion. 2002;42(12):1561–6.
18. Wollersheim J, Dautzenberg M, van de Griendt A, Sybesma B. Donor selection criteria to maximize double platelet components (DPP) by platelet apheresis. Transfus Apher Sci. 2006; 34(2):179–86.
19. Chaudhary R, Das SS, Khetan D, Sinha P. Effect of donor variables on yield in single donor plateletpheresis by continuous flow cell separator. Transfus Apher Sci. 2006;34(2):157–61.
20. Yockey C, Murphy S, Eggers L, Garratty G, Dingle A, Helms C, Moroff G, et al. Evaluation of the Amicus separator in the collection of apheresis platelets. Transfusion. 1998;38(9):848–54.
21. Fontana S, Rados L, Schmid P, Leibundgut EO, Taleghani BM. Recruitment of platelets, white blood cells, and hematopoietic progenitor cells during high-yield plateletpheresis: blood cell recruitment during apheresis. Transfusion. 2011;51(9): 2034–43.
22. Keklik M, Eser B, Kaynar L, Solmaz M, Ozturk A, Yay M, Birekul A, Oztekin M, Sivgin S, Cetin M, Unal A. Comparison of double dose plateletpheresis on the Fenwal Amicus, Fresenius COM. TEC and Trima Accel cell separators. Transfus Apher Sci. 2014;51(2):193–6.
23. Jaipian J, Chuansumrit A, Chongkolwatana V, Kunakorn M, Kitpoka P. Collection efficacies of double dose platelet by blood cell separators. J Hematol Transfus Med. 2013;23(2):121–8.
24. Chaudhary R, Das SS, Khetan D, Ojha S, Verma S. Donor safety issue in high-dose platelet collection using the latest apheresis system. Transfus Altern Transfus Med. 2010;11(1):1–7.
25. Glicher RO, Smith JW. Apheresis: principles and technologies of hemapheresis. In: Simon LT, Snyder EL, Solheim BG, Stowell CP, Strauss RG, Petrides M, eds. Rossi's Principles of Transfusion Medicine, 4th ed., Blackwell Publishing Ltd; 2009:617–28.
26. Guerrero-Rivera S, Gutiérrez-Espíndola G, Talavera JO, Meillón-García LA, Pedraza-Echevarría M, Pizzuto-Chávez J. Hemoglobin and platelet count effect on platelet yields in plateletpheresis. Arch Med Res. 2003;34(2):120–3.
27. Enein AA, Hussein EA, El Shafie S, Hallouda M. Factors affecting platelet yield and their impact on the platelet increment of patients receiving single donor PLT transfusion. J Clin Apheresis. 2007;22:5–9.
28. Beyan C, Cetin T, Kaptan K, Nevruz O. Effect of plateletpheresis on complete blood count values using three different cell separator systems in healthy donors. Transfus Apher Sci. 2003;29(1):45–7.
29. Tendulkar A, Rajadhyaksha SB. Comparison on three continuous flow cell separators. Asian J Transfus Sci. 2009;3(2):73–7.
30. Das SS, Chaudhary R, Verma SK, Ojha S, Khetan D. Pre- and post- donation haematological values in healthy donors undergoing plateletpheresis with five different systems. Blood Transfus. 2009;7(3):188–92.
31. Keklik M, Korkmaz S, Kalan U, Sarikoc M, Keklik E. Effectiveness of the Trima Accel cell separator in the double dose plateletpheresis. Transfus Apher Sci. 2016;55(2):240–2.
32. Kumavat V, Goyal M, Marimuthu P. Analysis of donor safety in high yield plateletpheresis procedures: an experience from tertiary care centre in South India. Indian J Hematol Blood Transfus. 2020. https://doi.org/10.1007/s12288-020-01266-z.
33. Bertolini F, Rebulla P, Riccardi D, Cortellaro M, Remzi ML, Sirchia G. Evaluation of platelet concentrates prepared from buffy coats and stored in a glucose free crystalloid medium. Transfusion. 1989;29(7):605–9.