Original Article

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Study of Factors Affecting the Yield of Plateletpheresis by Intermittent Flow Cell Separator

Transfusion Medicine Section

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ABSTRACT

Introduction: Rational use of platelet transfusions is one of the important treatment options available. Due to advances in apheresis technology, collection of Single Donor Platelets (SDP) with high yield is achieved. Platelet yield in the transfused SDP product influences the platelet recovery in the patient thus decreasing repeated transfusions and economic burden.

Aim: To analyse donor laboratory and clinical factors influencing the quality of SDP.

Materials and Methods: A retrospective study on plateletpheresis procedures was conducted in the Department of Transfusion Medicine, at Kamineni Institute of Medical Sciences Telangana, India, from January 2017 to January 2019. A total of 168 procedures were studied which were done on intermittent flow cell separator (Haemonetics MCS+, USA). Donor variables such as age, gender, predonation platelet count, haemoglobin, Haematocrit, Total Leukocyte Count (TLC), Mean Platelet Volume (MPV), and Platelet Distribution Width (PDW) were studied for their effect on platelet yield of SDP. Statistical analysis was done for study of relationship between platelet yield and donor variables using Pearson correlation.

Results: The mean age was 26.8±5.81 years with maximum in age group 21-30 years. The mean platelet yield was $3.1\pm0.79\times10^{11}$ per unit. Statistically significant direct correlation was observed between predonation platelet count and platelet yield ($r=0.327$, $p<0.0001$). No such correlation was observed with predonation haemoglobin ($r=0.098$, $p=0.204$). There was a negative correlation between the platelet yield and MPV ($r=-0.051$, $p=0.512$) which was not significant. There was negative correlation between platelet yield and PDW ($r=-0.166$, $p=0.032$) which was found to be statistically significant. Also no statistical significance was found between platelet yield and age of the donor ($r=0.118$, $p=0.125$), total leukocyte count of the donor ($r=0.112$, $p=0.147$), haematocrit of the donor ($r=0.005$, $p=0.944$).

Conclusion: Donors with higher platelet counts results in a better yield and derives a better clinical response. This helps in decreasing the number of transfusions per patient and exposure to the donors thus lessening the economic burden.

Keywords: Blood, Cell separator, Platelet transfusion, Platelet yield, Single donor platelets

INTRODUCTION

Advances in transfusion medicine have increased exponentially in the past few years with the introduction of advanced cell separators which have defined platelet therapy in terms of quality and productivity [1]. Apheresis technology is widely available in developed countries and at some centres in developing countries like India. Apheresis is a process in which blood is removed from a subject and separated into components, allowing the desired component (components) to be retained while the remainder is returned to the subject. Single Donor Platelets (SDP) derived from the plateletpheresis procedure is equivalent to 6-8 random donor platelet concentrates derived from whole blood [1].

Automated apheresis techniques were first developed in 1975 and since then have undergone several technical modifications and standardisation resulting in reproducibility of the collection process and the platelet yield. Thus without operator interference, the final platelet yield relate primarily to the biologic contribution of the donor (platelet count, total mass) [1,2].

Single donor platelets has large numbers of platelets from a single donor, thereby providing a more consistent product dose with fewer donor exposures for the patient thus decreases repeated transfusions, alloimmunisation, platelet refractoriness development, risk of disease transmission, and rate of febrile non haemolytic reactions [2,3].

Platelet recovery in the patient is influenced by the transfused dose of platelets, which in turn is dependent on the quality of the platelet product in terms of yield [1,2]. It has been shown that transfusion of high yield platelet products could reduce transfusion requirements of a thrombocytopenic patient. Platelet yield is related to the donor variables like platelet count, total mass [3,4].

With the increasing usage of the SDPs in thrombocytopenia patients, the need for the eligible donors also increased where donor related demographic and laboratory factors influence the platelet yield. Many studies were done in relation with only few factors like donor predonation platelet count and haemoglobin affecting the platelet yield and other factors but still there is ambiguity in relationship [1,2,4]. This study was planned to analyse both donor demographic and haematological factors as age, predonation platelet count, haemoglobin, haematocrit, Total Leukocyte Count (TLC), Mean Platelet Volume (MPV), Platelet Distribution Width (PDW), affecting the platelet yield using an intermittent cell separator. Each blood bank should have donor data with all these factors which helps in ensuring product quality, safe and effective donor registry.

MATERIALS AND METHODS

A retrospective study on plateletpheresis procedures was conducted in the Department of Transfusion Medicine, in a multispeciality tertiary care hospital, Kamineni Institute of Medical Sciences Telangana, India, from January 2017 to January 2019. Data was analysed from May 2021 to August 2021. Informed consent was taken from the donors before donation stating that the data can be used for research purpose. Institutional Ethics Committee has given Ethical Clearance for the study. All the donors met the donor eligibility criteria as laid down by the Drugs Controller of India and the procedures performed strictly according to the standard operating procedures of the blood bank.

Inclusion criteria: Donors were either voluntary or replacement donors selected with following criteria [5].

i. Age: 18-60 years
ii. Weight >50 kg
iii. Haemoglobin (Hb) >12.5 gm%
iv. Platelet count >150×10^3/cumm
v. 28 days interval from last whole blood donation
vi. 48 hours interval from last apheresis donation
vii. Negative for Human Immunodeficiency Virus (HIV), Hepatitis B and C Viruses (HBV and HCV) malaria and syphilis.

Exclusion criteria: Platelet donors follow the same exclusion criteria as whole blood donors. They are permanently deferred if tested positive for HIV, HBV, and HCV. Temporary deferral if they have a history of aspirin drug intake or any antiplatelet drugs.

Haematological parameters of donor were measured on whom quality assurance was done with internal and external controls by Pathology Department. Donors were selected based on these parameters and informed consent was taken.

Study Procedure

The study includes 168 plateletpheresis procedures performed on intermittent flow cell separator (Haemonetics MCS+, USA) using single venous access closed system apheresis kits. After the donor selection and their consent, apheresis kits were installed on the cell separator and priming was initiated. Antecubital veins were used for venipuncture in all the donors. Vital signs were monitored at the beginning and end of each procedure; they were also monitored for adverse events during the procedures. The blood flow rate for all procedures was maintained at 40-50 mL/min with an anticoagulant Acid Citrate Dextrose Solution-A (ACD-A) ratio of 12:1. The total amount of blood processed, volume of Acid Citrate Dextrose (ACD) solution used and product volume for each procedure were documented.

Donor demographic parameters such as age and gender were noted. Haematological parameters like haemoglobin, platelet count, Total Leukocyte Count (TLC), Mean Platelet Volume (MPV), and Platelet Distribution Width (PDW) are measured in predonation samples which were collected in Ethylenediamine Tetraacetic Acid (EDTA) vacutainers from each donor. Tube segment of the platelet bag is thoroughly stripped using a handheld stripper, then 1 mL of the sample was collected in EDTA vacutainer from platelet bag for assessing platelet count of the product.

The platelet yield was calculated using the formula: platelet yield=product volume (mL)×product platelet count (platelets/μL)× conversion factor (1000).

STATISTICAL ANALYSIS

Influence of the donor variables on the yield of platelets was studied by using Pearson correlation coefficient and multivariate linear regression analysis by calculating r value using Microsoft Excel. All statistical tests were two-sided and performed at a significance level of α=0.05. A p-value of <0.05 was taken as significant.

RESULTS

A total of 168 donors who fulfilled the donor eligibility criteria underwent plateletpheresis procedures on intermittent flow cell separator during the study period of three years. Mean age of the donor was 26.8±5.8 years [Table/Fig-1] with 100% replacement donations and all were male donors (100%), majority (70.3%) of the donors distributed in the age group of 21-30 years [Table/Fig-2]. The mean value of predonation haemoglobin was 14.9±1.6 gm/dL and mean predonation platelet count was 269.2±49.4×10^3/μL [Table/Fig-1]. Majority of donors (75%) have a predonation platelet count of 201-300×10^3/μL [Table/Fig-3].

Mean blood volume processed was 2417±367 mL by using 299±41.4 mL of ACD solution. The Mean volume of the single donor apheresis product obtained was 222.5±28.8 mL and the mean platelet yield of all procedures was 3.1±0.79×10^{11} per unit. Total 60% of the single donor apheresis platelets obtain a platelet yield of >3×10^{11} per unit [Table/Fig-4].

Parameter	Mean±SD	Range
Age (years)	26.8±5.81	19-48
Haemoglobin (gm/dL)	14.9±1.6	12.6-18.4
Haematocrit (%)	45.5±3.5	33.4-57.6
White blood cells count (/μL)	8.3±1.7	5-14.2
Platelets count (10^3/μL)	269.2±49.4	163-450
Platelet distribution width (%)	15.3±0.6	12.5-16.8
Mean platelet volume (fL)	8.4±0.7	6.8-11

[Table/Fig-1]: Donor Factors and their Mean, SD and range.

Age (years)	Number of donors, %
18-20	15 (9%)
21-30	118 (70.3%)
31-40	28 (16.6%)
41-50	7 (4.1%)

[Table/Fig-2]: Distribution of age in plateletpheresis donors.

Predonation platelet count (×10^3/μL)	Number of donors, %
150-200	2 (1.2%)
201-300	126 (75%)
301-400	38 (22.6%)
>400	2 (1.2%)

[Table/Fig-3]: Distribution of predonation platelet count among donors.

Platelet yield (×10^{11}) per unit	Number of donors, %
<2	14 (8.4%)
2.1-2.5	16 (9.5%)
2.6-3.0	44 (26.1%)
>3.0	94 (60%)

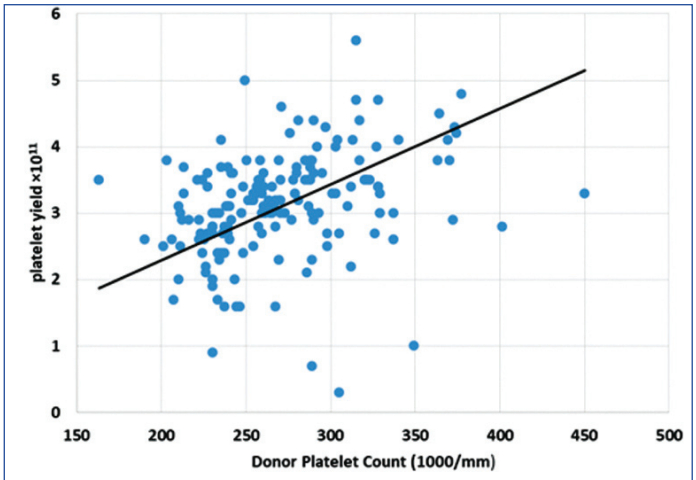
[Table/Fig-4]: Distribution of platelet yield among donors.

All the donors were divided into three groups based on the predonation platelet count (group 1:150-200×10^3/μL, group 2: 200-300×10^3/μL, group 3: >300×10^3/μL). Out of 168 donors, only two donors were in group 1, 126 donors in group 2 and 40 donors in group 3. The platelet yield of ≥3 ×10^{11} per unit was seen in 50% of group 1 donors, 60.3% in group 2 and 80% in group 3 [Table/Fig-5]. The platelet yield consistently increased from group 1 to 3 with increase of predonation platelet count. [Table/Fig-6] showed a direct correlation between the predonation platelet count and platelet yield (r=0.327, p<0.0001). The yield of platelets was ≥3×10^{11} per unit in 80% of procedures when the predonation platelet count was >300×10^3/μL [Table/Fig-5].

Platelet yield (%)	Group 1 (150-200×10^3/μL, n=2)	Group 2 (200-300×10^3/μL, n=126)	Group 3 (>300x10^3/μL, n=40)	All n=168
Mean±SD	3.05±0.6	3.02±0.7	3.5±0.9	3.1±0.7
Median	3.05	3.05	3.5	3.2
Range	0.9	4.3	5.3	5.3
≥3×10^{11} (%)	50%	60.3%	80%	64.8%

[Table/Fig-5]: Distribution of predonation platelet count with yield.

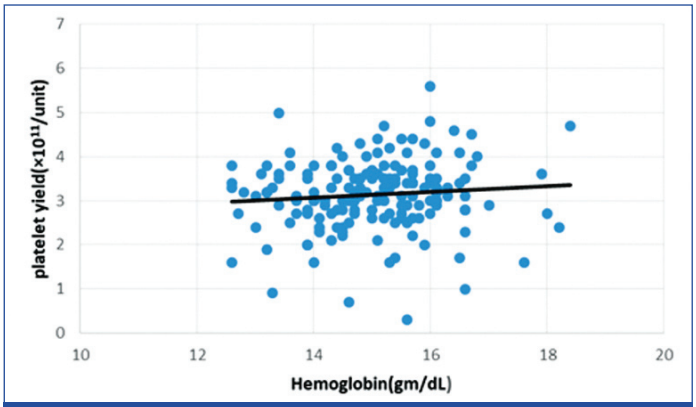
The platelet yield of ≥3×10^{11} per unit was seen in 61.5% of donors with Hb<15 gm% and 66.6% of donors with Hb>15 gm% [Table/Fig-7]. [Table/Fig-8] showed that there was no significant correlation between predonation Hb and the platelet yield obtained in the product (r=0.098, p=0.204). Out of 168 donors, 78 had Haemoglobin (Hb) 15 gm% and remaining 90 had Hb>15 gm%.



[Table/Fig-6]: Correlation between predonation platelet count and platelet yield (r=0.327, p<0.0001).

Platelet yield×10¹¹	Donor Hb <15 gm/dL (n=78)	Donor Hb ≥15 gm/dL (n=90)
Mean±SD	3.0±0.7	3.2±0.8
Median	3.1	3.3
Range	4.3	5.3
≥3×10¹¹ (%)	61.5%	66.6%

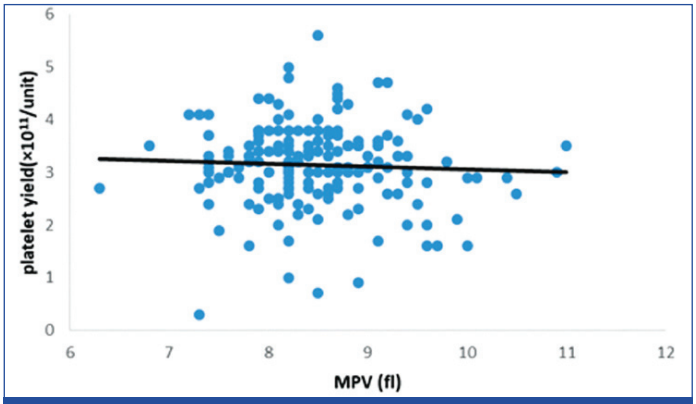
[Table/Fig-7]: Distribution of predonation haemoglobin with yield.



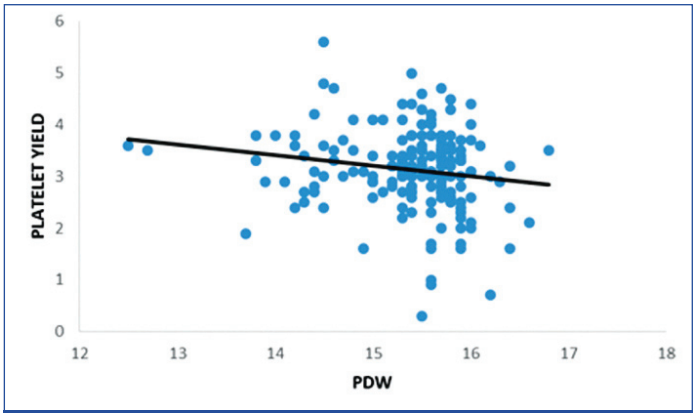
[Table/Fig-8]: Correlation between predonation haemoglobin and platelet yield: (r=0.098, p=0.204).

There was a negative correlation between the platelet yield and MPV (r=-0.051, p=0.512) which was not significant [Table/Fig-9]. There was negative correlation between platelet yield and PDW (r=-0.166, p=0.032) which was found to be statistically significant [Table/Fig-10].

No statistical significance was found between platelet yield and age of the donor (r=0.118, p=0.125), TLC of the donor (r=0.112, p=0.147), haematocrit of the donor (r=0.005, p=0.944).



[Table/Fig-9]: Correlation between predonation MPV and platelet yield: (r=-0.051, p=0.512).



[Table/Fig-10]: Correlation between predonation PDW and platelet yield: (r=-0.166, p=0.032).

DISCUSSION

Various studies have demonstrated the rise in usage of SDPs than platelet concentrates obtained from the whole blood donation [6]. Advances in automated cell separators have paved a way to improve the collection process of apheresis and thus the quality and quantity of the platelet product. Thus decreasing the cellular contamination and increasing the platelet yield [7].

According to American Association of Blood Banks (AABB) guidelines [8], 75% of the SDP products should contain a platelet count of ≥3×10¹¹ per unit and European guidelines [9] recommend >2×10¹¹ per unit. These levels of platelet dose are sufficient for a desired response in the patients. In India, guidelines for SDP are laid down by the drugs controller of India which are platelet count of ≥3×10¹¹ per unit with red cell contamination of <0.5 mL and WBC contamination of <5×10⁶ per unit [5]. In present study, out of 168, 108 SDPs (64.2%) have met the AABB and Indian criteria with a yield of ≥3×10¹¹ per unit and 156 SDPs (92.8%) have fulfilled European guidelines with a yield of >2×10¹¹ per unit. A 79% of SDPs have met the AABB criteria when the predonation platelet count was 250×10³/mm. Comparison to this study, only 41.5% have met AABB criteria by Chaudhary R et al., 32.8% by Das SS et al., 66.1% by Arun R et al., [10-12]. European guidelines have been met in other studies with 100% in Das SS et al.,93% in Arun R et al., study [11,12].

Different trials have shown that predonation donor platelet count was directly related to the platelet yield of the product. It means a high platelet count of the donor which implies that more platelets are available for collection results in high platelet yield [1,2,11] (Goodnough LT et al.,Guerrero-Rivera S et al., Chaudhary R et al.,). A study by Goodnough LT et al., show that a high dose of platelets could decrease the number of platelet transfusions required by thrombocytopenic patients and thus decreasing the economic burden on the patients [2]. There are several predictors for determining the platelet yield and by gaining knowledge of these factors, we can maximise the donor pool and ensure the product quality [13].

Goodnough LT et al., studied 708 plateletpheresis procedures which have a mean predonation platelet count of 237±49×10³/μL and mean platelet count of 4.24±1.1×10¹¹ per unit [2]. A statistically significant direct linear correlation is observed in their study for all the procedures (r^2=0.50, p<0.001). Similarly, in a study by Chaudhary R et al., 94 procedures were studied which also found a direct correlation between the predonation platelet count and platelet yield (r=0.50, p<0.001) [10]. Das SS et al., studied 61 procedures which also indicated good linear correlation between the predonation platelet count and platelet yield (r=0.51, p<0.001) [11]. In the present study, mean predonation platelet count of 168 donors was 270.5±45.6×10³/μL with a mean platelet yield of 3.13±0.79×10¹¹ per unit. Results of the present study were also found in accordance with the above studies and have a statistically

significant linear correlation between the predonation platelet count and platelet yield (r=0.327, p<0.001).

Another donor factor that is studied is the predonation haemoglobin concentration of the donor and its effect on platelet yield. Various studies were done by Ogata H et al., Chaudhary R et al., and Das SS et al.,have shown that there is no correlation between predonation Hb and platelet yield [7,10,11]. Similarly in the present study also, authors found that there is no significant correlation between platelet yield and predonation Hb (r=0.098, p=0.204). Predonation Hb ≥15 gm/dL was noted in 78 out of 168 donors. Out of them, 61.5% had a platelet yield of $\geq 3\times10^{11}$ per unit. A 66.6% of donors with predonation Hb<15 gm/dL (90/168) had a platelet yield of $\geq 3\times10^{11}$ per unit. A study done by Guerrero-Rivera S et al.,found an inverse relationship between predonation Hb and platelet yield which may be related to processing higher plasma volume in donors with low Hb which results in higher platelet yield [1].

A study on the influence of donor haematocrit on yield was done by Chellaiya GK et al.,on two cell separators found no correlation between platelet yield and donor haematocrit [14]. In this study, authors also found no correlation between platelet yield with predonation haematocrit (r=0.005, p=0.944).

There was a negative correlation between the platelet yield and MPV (r=-0.051, p=0.512) which was not significant. There was negative correlation between platelet yield and PDW (r=-0.166, p=0.032) which was found to be statistically significant. A study done by Sachdeva P et al., using a continuous flow cell separator found a direct negative correlation between the MPV and platelet yield (p<0.001) [15]. This was attributed to the separation mechanism in the Amicus cell separator which is based on cell size. Larger size platelets resemble red cells hence they are not collected efficiently by the machine but smaller platelets are collected efficiently, thus extracting better yield.

Predonation WBC count was studied for its effect on platelet yield and found that there was no significant correlation (p>0.001) between them in this study. Another factor studied was the age of the donor affecting the platelet yield. There is no significant correlation observed (p>0.01) in this study and similar results are observed in Chaudhary R et al., Buchholz DH et al., and Bahadur S et al., [10,16,17].

Limitation(s)

Study population was small and correlation between platelet yield and the patient outcome could not be established. Gender correlation also could not be analysed. There is a need for multi centric study for understanding more of such factors affecting the platelets yield.

CONCLUSION(S)

Direct correlation between platelet count of the donor and the platelet yieldis established which is a similar finding in many studies. No correlation was found between platelet yield and haemoglobin. Donors with higher platelet counts results in a better yield and derives a better clinical response.This helps in decreasing the number of transfusions per patient and exposure to the donors thus lessening the economic burden. Each blood bank should maintain a donor database with their demographic and haematological parameters which helps in obtaining a high quality and safe SDP product.

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- Manual Googling: Oct 28, 2021
- iThenticate Software: Oct 23, 2021 (21%)

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