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Effect of donor parameters and cell separators on yield of apheresis platelet and their impact on corrected count increment in aplastic anemia patients

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Abstract:

BACKGROUND: The new cell separators make it simple to collect single donor platelets (SDP), although the platelet yield may vary depending on the cell separator used and donor-related clinical and laboratory variables.

AIMS: This study aims to study the factors affecting SDP yield and corrected count increment (CCI).

MATERIALS AND METHODS: This retrospective study was carried out at a tertiary care facility in northern India, over 4 years (May 2017–April 2020), data were retrieved and analyzed.

STATISTICAL ANALYSIS: Categorical variables were presented as proportions, while continuous variables were presented as mean with standard deviation, $P < 0.05$ was considered significant.

RESULTS: We found a positive correlation between predonation platelet count and yield ($r = 0.243$, $P = 0.000$). No such significant correlation was found with Hb concentration ($r = 0.025$, $P = 0.720$), age ($r = 0.016$, $P = 0.820$), sex ($r = -0.038$, $P = 0.584$), and weight ($r = -0.025$, $P = 0.714$). Maximum platelet yield and minimum time were seen with Trima. Only 39.3% (33/84) meet the 24 h CCI. The majority of patients did not meet the desired CCI could be due to the patients' clinical condition. On logistic regression, we found a significant association of 24 h CCI with product yield (odds ratio [OR] = 0.168, $P = 0.015$) and posttransfusion platelet count (OR = 0.454, $P < 0.05$).

CONCLUSION: The only donor-related factor that influences yield is predonation platelet count, whereas 24 h CCI may depend on the clinical status of the patient and yield.

Keywords:

Aplastic anemia, corrected count increment, cells separators, donor variables, platelet yield

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Introduction

Since its advent, apheresis platelet concentrates collected from single donor also known as single donor platelets (SDPs) are being used as supportive therapy in thrombocytopenic conditions, hematological malignancies, or as a component of massive transfusion. In comparison to random donor platelet concentrates separated of whole blood (WB) collections, SDPs have been observed to have certain advantages such as better platelet yield, lesser cellular contamination and transfusion reactions, as well as limited donor exposure, thereby reducing the risk of transfusion-transmitted infections and alloimmunization and have few disadvantages such as higher cost and increased time required for collection.[1]

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Since 1975, automation and various technological advancements in apheresis have undergone several modifications and standardization to meet the increasing requirement of platelet concentrates faced by the blood transfusion services (BTS).[2] The latest-generation apheresis machines have been designed to achieve better platelet quality with due importance to donor safety.[3]

Although the principle of separation (centrifugation) in cell separators is generally the same, various technical differences can affect the quality of SDP obtained.[2] The biggest factors for determining whether a donation will produce a high platelet yield were the donor's platelet count.[4] The recovery of platelets in the patient is influenced by the dose of platelets transfused. Transfusion of platelet products with high platelet yield could decrease the transfusion requirements of a thrombocytopenic patient.[2] Corrected count increment (CCI) is used to assess response to platelet transfusion and determine platelet recovery and platelet survival as well as to diagnose platelet refractoriness.[5] CCI depends on platelet increment per microliter, body surface area (BSA) in square meters (m^2) and number of platelets transfused ($\times 10^{11}$).[6]

Previous studies have compared different apheresis machines[7] with regard to platelet yield and quality; however, the introduction of newer machines with increasing efficacy makes it imperative for comparative studies to be undertaken by the BTS. We undertook this retrospective study to understand better the effect of different apheresis machines and influence of donor variables on the yield of SDPs and their CCI on aplastic anemia patients who are among the predominant consumers of SDPs in our institute.

Materials and Methods

This study was conducted in the Department of Transfusion Medicine in a tertiary care referral institute in Northern India, over 3 years (May 2017–May 2020). The study being of retrospective and observational in nature, waiver of consent was obtained from the institute ethics committee. Donors' and patients' identifiers were anonymized to maintain confidentiality.

Healthy donors are required to fill in the donor history questionnaire and consent form, undergo a brief health evaluation and medical examination by the transfusion physician, following which they are deferred/selected for SDP donation in accordance with departmental protocols adopted from national guidelines.

Three different single-needle apheresis machines are used for collection of SDP: Fenwal Amicus (Fenwal, Lake Zurich, IL), COM.TEC (Fresenius HemoCare GmbH, Bad Homburg, Germany), TrimaAccel (COBE-Trima 1998, Lakewood, USA). Before donation, the following data are entered into cell separator program for all devices: donors' weight, gender, height, hematocrit, and platelet count. The processed blood volume to reach the target platelet yield (3×10^{11}) was determined by the devices' softwares. No additional postprocedure processing or filtration to obtain leukoreduced products was performed.

The parameters used for the comparison of machines were platelet yield (one hour) and time is taken to complete the procedure. The time duration was calculated from the initiation of inlet draw of WB by the machine till the time of needle removal.

Platelet yield was calculated using the formula: Yield = product volume × platelet count/µl

All SDP procedures were performed following the departmental standard operating procedure using sterile closed system apheresis kits and Acid Citrate Dextrose-A (ACD-A) anticoagulant in the proportion of 1:10–1:12. Target yield of 3×10^{11} platelets per unit was set for all the procedures while maintaining a blood flow rate of 50–80 ml/min depending on the machine.

A sample for platelet count was taken from the sample pouch after thorough stripping of the segment and run on automated cell counter (Medonic M Series, Sweden).

Donor parameters such as age, sex, height, weight, predonation hemoglobin (Hb), and hematocrit and SDP procedure details such as time taken to complete the procedure, plasma volume collected, ACD used, total blood volume (TBV) processed and platelet yield were noted for each procedure from the procedure register.

Patient's physiognomic factors including diagnosis, age, sex, height, weight, and pretransfusion platelet counts, infection, and drug history are recorded from SDP requisition forms and hospital information system.

BSA was calculated using the Mosteller formula:

$$\text{BSA } (m^2) = \frac{\sqrt{\text{height(cm)} \times \text{weight (kg)}}}{3600}$$

platelet dose for all machines was calculated by formula:

$$= \frac{\text{platelet yield}}{\text{BSA}}$$

The posttransfusion platelet counts (after 24 h of transfusion) are recorded from the hospital information system.

CCI is calculated using the following formula:

CCI = Platelet increment per ul x BSA in m^2/number of platelets transfused ($\times 10^{11}$)

Twenty-four hours CCI ≥4500 is considered satisfactory.

Aplastic anemia patients with similar BSA were included and ABO incompatible product were excluded from the study. Records were retrieved from SDP procedure registers and HIS.

Statistical analysis

All statistical tests were performed using IBM SPSS software for Windows version 20 (IBM Corp, Armonk, NY, USA), Continuous variables were presented as mean with standard deviation, whereas categorical variables were presented as number and percentage. Pearson correlation and binary logistics were used and $P < 0.05$ was considered statistically significant.

Results

Only 210 SDP procedures were carried out for people with aplastic anemia during the study period, out of a total of 210 SDP procedures. 76 (36.2%) of these procedures were performed on the Fenwal Amicus, 70 (33.3%) on the Trima Accel, and 64 (30.5%) on the COM.TEC. Majority of the donors were male 97.1% (204/210). The mean age, weight, and height of donors were 30.3 ± 8.98 years, 74.8 ± 11.77 kg, and 169.9 ± 6.53 cm, respectively. The donor characteristics were comparable across the three groups of cell separators [Table 1].

Predonation platelet count of the donor was shown to have a statistically significant positive link with platelet yield among the donor characteristics [Table 2] ($r = 0.408$, $P < 0.001$).

No significant correlation was found between platelet yield and other donor parameters (age, height, weight, and Hb).

In comparison to Fresenius, Trima, and Amicus had the highest platelet yield and finished the process in the shortest amount of time ($P < 0.05$) [Table 3]. The amount of total ACD utilized, and the volume of the product collected was different across the three machines, and this variation was statistically significant ($P < 0.05$).

A total of 84 patients (59 males and 25 females) with aplastic anemia received 210 units of SDP. The mean age, weight, height, and BSA of the patients were 37.6 ± 13.75 years, 63.1 ± 11.19 kg, 164 ± 12.64 cm, and 1.69 ± 0.19 kg/m^2, respectively.

We calculated 24 h of CCI and divided patients into two groups [Table 4]. No statistically significant difference was found between platelet yield among these two groups.

Only 33 patients (39.2%) reached the 24 h CCI, while the remaining 51 patients (60.7%) did not. Patients' clinical conditions and medication are given in Table 5.

The majority of patients with <4500 CCI had sepsis and were on either antifungal, antibacterial, or both medications (54.9%, 28/51).

Using univariate analysis, we found that platelet yield (odds ratio [OR] = 0.168, $P = 0.015$) and posttransfusion platelet count (OR = 0.454, $P = 0.000$) significantly influenced CCI, whereas patient weight showed a significantly negative association (OR = –0.144, $P = 0.037$) with CCI [Table 6].

Multivariate analysis revealed a significant independent association between CCI and the posttransfusion platelet count (adjusted OR = 0.430, $P < 0.001$) only.

Discussion

The quality of SDP in terms of yield is one of the parameters used to objectively assess platelet recovery in the recipient.[8] Platelet yield has been observed to be influenced by the donor's predonation platelet count and Hb concentration: the higher the platelet count, the higher the yield, but there is inverse relation with Hb.[9] Platelet yield has also been found to be higher in female donors as compared to male donors because females usually have lower Hb as a result of iron deficiency and also due to lower levels of the hormone testosterone.[10]

Among the donor characteristics considered in the current study, we found that the donor's predonation platelet count had a substantial impact on platelet yield. Previous studies by Das *et al*.,[11] Guerrero-Rivera *et al*.,[9] and Enein *et al*.[12] reported similar findings.

Table 1: Comparison of donor characteristics across the three-cell separators in our study

Donor parameters	Mean±SD			*P*
	Fenwal-Amicus (*n*=76)	COM.TEC (*n*=64)	Trima Accel (*n*=70)	
Age (years)	31.6±8.94	28.9±8.18	30.1±9.66	0.109
Males/females	73/3	64/-	67/3	
Weight (kg)	74.2±11.99	76.4±12.47	73.8±10.85	0.438
Height (cm)	169.1±5.77	170.8±7.38	170±6.47	0.119
Predonation platelet count (/μL)	178±12.2	177.8±15.7	175.7±14.5	0.132

SD=Standard deviation

Although previous research suggested that platelet yield has an inverse relationship with Hb,[9] we found no such relationship. Similar to that our study, Das *et al*.[4] also did not find a relation between platelet yield and Hb. Buchholz *et al*.[13] observed that donor weight has little impact on platelet yield. We also observed a nonsignificant negative correlation between donor weight and platelet yield.

In the current study, we found that Trima Accel and Amicus produced noticeably better yield than COM.TEC, regardless of the predonation platelet count and other parameters that were similar across the three cell separators. However, there was no discernible difference in maximum yield between Trima and Amicus. Our results were in line with those of a prior study by Keklik *et al*.[14] who found that COM.TEC dramatically reduced platelet yield when compared to Trima and Amicus.

In terms of how long it took to reach the target yield, we also noticed big disparities between the three devices. Trima took the shortest length of time, followed by Amicus and COM.TEC. Prior research by Altuntas *et al*.[15] and Philip *et al*.[16] revealed that COM.TEC took noticeably more time than Amicus (74 vs. 68 min and 61 vs. 44 min in the respective studies). The separation time between Trima and Amicus, which was identical to that previously noted by Keklik *et al*.,[14] did not significantly differ in the current study.

With regard to the TBV processed to achieve the desired yield, we saw a substantial disparity between the three devices. However, when compared between Amicus and Trima, there was no appreciable difference in this. According to Altuntas *et al*.,[15] COM.TEC processed considerably more median blood volume than Amicus to achieve a platelet yield of $\geq 3.3 \times 10^{11}$/unit (3481 vs. 2850 ml; $P < 0.001$). However, Philip *et al*.[16] found no significant difference (2972 vs. 2853 mL; $P > 0.05$) between Amicus and COM.TEC in the median blood volume processed to achieve the required PLT yield (3×10^{11}/unit).

Another parameter, collection rate (CR), which simultaneously considers platelet yield and processing time, is utilized in the real world to compare various platelet-pheresis machines. However, this parameter was found to be lower for COM.TEC (0.041 ± 0.008/min) compared to Trima (0.061 ± 0.018/min) and Amicus (0.057 ± 0.017/min.), despite there being no statistically significant difference in CR ($P = 0.264$) among the three devices.

A related observation was reported by Altuntas *et al*.[15] and Philip *et al*.[16] also found comparable CR in Amicus and COM.TEC.

According to 24 h CCI, patients were divided into two groups in the current study [Table 4] and we found

Table 2: Correlation of donor parameter with yield

Variables	Correlation coefficient (*r*)	*P*
Age (year)	0.016	0.820
Height (cm)	0.023	0.742
Weight (kg)	−0.025	0.714
Hb (g/dL)	0.025	0.720
Predonation platelet count (/μL)	0.243	<0.001

Hb=Hemoglobin

Table 3: Comparison of procedure parameters and platelet yield of different plateletpheresis machines

Variables	Mean±SD			*P*
	Trima (*n*=70)	Amicus (*n*=76)	COM.TEC (*n*=64)	
Platelet yield×10^{11}	3.12±0.31	3.11±0.36	2.92±0.40	<0.001
Time (min)	56.0±12.5	57.8±13.2	70.9±13.4	<0.001
TBV processed (mL)	2525±462	2596±413	3299±596	<0.001
ACD used (mL)	256.5±47.8	294.4±54.9	356.1±80.6	<0.001
Product volume	196.2±6.4	223.2±13.9	297.8±9.4	0.028
CR*	0.061±0.018	0.057±0.017	0.041±0.008	0.264

CR=Platelet yield/time (min). TBV=Total blood volume, CR=Collection rate, SD=Standard deviation, ACD=Acid citrate dextrose. *Collection rate indirectly measure the collection efficiency

Table 4: Correlation of corrected count increment with yield

CCI (24 h)	<4500 (*n*=51)	≥4500 (*n*=33)	*P*
Yield ×10^3 (mean±SD)	2.91±0.39	3.0±0.49	0.145
Yield ×10^3 (range)	2-4.5	1.88-3.9	

SD=Standard deviation

Table 5: Clinical condition and medication of patients

Clinical condition and medication	CCI <4500 (*n*=51; 60.7), *n* (%)	CCI ≥4500 (*n*=33; 39.3), *n* (%)
ATG	6 (11.7)	18 (54.5)
ATG + antifungal medication	3 (5.88)	4 (12.1)
Sepsis + antibiotics	5 (9.80)	2 (6.06)
DIC + antibiotics	5 (9.80)	1 (3.03)
Sepsis + antibiotic + antifungal medication	15 (29.4)	3 (9.09)
Post-BMT with sepsis + antibiotic + antifungal	13 (25.4)	3 (9.09)
Post-BMT with fever + antibiotics	-	2 (6.06)
Fungal pneumonia	1 (1.96)	-
On immunosuppressant	3 (5.88)	-

ATG=Antithymocyte globulin, BMT=Bone marrow transplant, CCI=Corrected count increment, DIC=Disseminated intravascular coagulation

Table 6: Univariate linear regression analysis to see the association of corrected count increment with yield and patient parameters

Variables	Regression coefficient (β)	OR	*P*
Platelet yield $\times 10^{11}$	2732.921	0.168	0.015
Age (years)	−25.4	−0.072	0.299
Weight (kg)	−62.3	−0.144	0.037
Height (cm)	−31.9	−0.068	0.325
BSA (m2)	−2972	−0.125	0.070
Pretransfusion platelet count $\times 10^3$/uL	21.4	0.091	0.190
Posttransfusion platelet count $\times 10^3$/uL	91.5	0.454	<0.001

CCI=Corrected count increment, OR=Odds ratio, BSA=Body surface area

39.3% (33/84) of our study population had satisfactory CCI. In addition to platelet yield, a number of other parameters, such as fever, splenomegaly, bone marrow transplantation,[17] and the presence of HLA antibodies[18] affect the CCI. Shastry and Chaudhary previously observed splenomegaly and the use of antiplatelet drugs to have a significant influence on CCI.[6] Our findings could be attributed to these patients having sepsis, fungal infection, fever disseminated intravascular coagulopathy, and bone marrow transplant during the study. Majority of patients in the current study with CCI <4500 were on antibiotics and/or antifungal medications in view of sepsis while most patients on ATG alone which had CCI of ≥4500 [Table 5].

Age, BSA, and pre- and post-transfusion platelet counts were also evaluated as patient-related factors for CCI assessment. Only the patient's posttransfusion platelet count was found to significantly affect CCI. The fact that this parameter is taken into account in the CCI calculation may be the cause.

Conclusion

Predonation platelet counts were found to significantly affect the production of SDP when considering donor parameters. Compared to COM.TEC, the parameters of TRIMA and AMICUS were more similar.

Apart from platelet yield, the clinical status of the patient is additional factor that affect CCI, which means that the collection device parse has little to no effect on it. We hope that the findings of our study together with future prospective studies in this area will help us choose the best apheresis equipment and patient characteristics that influence the CCI in the future.

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Conflicts of interest
There are no conflicts of interest.

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