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Research Article

Assessment of factors affecting the platelet yield using continuous flow cell separator

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Abstract

Background: The quality of single donor platelets (SDP) in terms of yield influences the platelet recovery in the recipient. Various donor factors such as predonation platelet count and hemoglobin concentration may affect platelet yield. The aim of present study was to assess the effect of various donor factors on platelet yield and effect of plateletpheresis on hematological values of donors.

Materials and methods: A total of 171 plateletpheresis procedures were performed using continuous flow cell separator (Amicus Automated Blood Collection System version 2.52/3.1) were evaluated for platelet yield. The pre and post donation hematological values such as platelet count, hemoglobin (Hb) concentration, mean platelet volume (MPV) and platelet distribution width (PDW) were measured in all blood donors.

Results: The mean platelet yield was 3.8 $\pm$ 1.65 X 10^{11} /unit. The platelet yield correlated positively ($r = 0.446$, $p < 0.001$) with donor pre –platelet count and negatively ($r = -0.004$, $p = 0.954$) with donor pre-Hb. There was significant increase ($p < 0.001$) in Hb concentration and platelet count decreased significantly ($p<0.001$) after each procedure. While, there was no significant decrease in MPV and PDW after each procedure.

Conclusion: All transfusion centers should have their own plateletpheresis donor data based on demographic and hematological characteristics of the donor population. This will ensure donor safety, product quality and an effective donor registry.

Keywords: Plateletpheresis, donor hematological parameters, cell separator, donor safety, platelet yield

1. Introduction

Single donor platelet (SDP) products are preferred over random donor platelet (RDP) products due to several advantages, such as support for patients with special needs, supplementation of platelet inventory, limited donor exposure and reduced transmission of infections[1-3]. Therefore, the focus has now shifted to use of SDP than pooled platelets. Automated apheresis techniques were introduced in 1975 and since then have undergone technical modifications and standardization to meet the platelet inventory needs of transfusion services. The new generation cell separators have made it possible to obtain high quality platelets with minimum donor manipulation. The transfusion medicine specialist is not only concerned with the collection of platelets but also pays attention to optimize the product in terms of balancing the platelet yield with the predonation and post donation hematological changes in the donors [4,5].

Platelet recovery in the patient is influenced by dose of platelets, which in turn is dependent on the quality of platelet product in terms of yield [6]. It has been shown that transfusion of high yield platelet products could reduce transfusion requirements of thrombocytopenic patients[7]. Plateletpheresis procedures are thought to be generally safe without serious complications. With the new cell separators, donor related factors both clinical and laboratory might control the platelet yield. The aim of present study was to analyze various donor factors such as predonation platelet count, hemoglobin (Hb) concentration, mean platelet volume (MPV) and platelet distribution width (PDW) on the yield of platelets and to determine the effect of plateletpheresis procedures on donor hematological parameters.

2. Materials and methods

The study included 171 (169 males and 2 females; aged from 20 to 52 years) plateletpheresis procedures performed on continuous flow cell separator (Amicus Automated Blood Collection System version 2.52/3.1) using closed system apheresis kits over a period from January 2009 to July 2010 at our department. All the donors met the donor eligibility criteria as laid down by the Drugs Controller of India[8]. Hematological parameters such as platelet count and Hb concentration were measured on an automated analyser (Cell Tech Automated Cell Counter ISE, Sr. l Rome, Italy).

The plateletpheresis procedures were performed as per the standard operating procedure (SOP) of the department. It is a continuous flow centrifugation machine. The platelets are separated from the RBCs and WBCs in a belt shaped chamber with two compartments. After the elutriation process, platelets reside in hyper concentrated form, so called dry platelets within the collection chamber until being manually re suspended in platelet poor plasma and transferred to the final storage bag. The maximum inlet rate varied from 45 ml/min to 150 ml/min with anticoagulant (ACD) infusion ratio of 10:1.

Pre and post-donation samples were collected in EDTA vial just before and after the procedure. Hematological parameters such as Hb, MPV, PDW and platelet count were measured on automated cell counter. After the procedure, it was ensured that the segment in the collected bag was kept approximately 15cm for sampling to calculate the platelet yield. Approximately 1ml of sample from each bag was collected after through stripping of the

segment to ensure representative product of the bag and subjected to determination of platelet count after appropriate dilution (1: 5) with sample diluents on an automated hematology analyzer or with ammonium oxalate for manual count on Neubauer Chamber to calculate the yield.

2.1 Statistical analysis

Influence of donor variables such as predonation platelet count and Hb% on the yield of platelets was studied by Pearson correlation coefficient and multivariate linear regression using SPSS Inc., Chicago, IL, and version 15.0 for Windows. All statistical tests were two-sided and performed at a significance level of $\alpha = 0.05$. A p value of < 0.05 was taken as significant.

3. Results

During the study period, a total of 171 healthy donors (mean age 28.1 ± 7.6 years) weighing 72 ± 11.1 kg underwent plateletpheresis procedures on continuous flow cell separator (Amicus Automated Blood Collection System version 2.52/3.1). The mean blood volume processed was 3030.7 ± 633 ml over the mean duration of 66.8 ± 14.3 minutes by using 400.5 ± 67.1 ml of acid citrate dextrose (ACD). After each procedure , Hb concentration increased from 13.6 ± 1.6g/dl to 15.3 ± 1.2 g/dl and hematocrit (hct) increased from 42.7 ± 3.4 % to 43.43.6 ± 3.6 %, the difference was found to be statistically significant ($p < 0.001$). The platelet count deceased from 241 ± 57.1 x 10^3/µl to 170.28 ± 48.86 × 10^3/µl after plateletpheresis and was found to be statistically significant (30%; $p < 0.001$). However, the decrease in MPV & PDW was not statistically significant. The changes in the donor hematological variables before and after plateleletpheresis are summarized in Table 1.

Table1: Hematological values before and after plateletpheresis

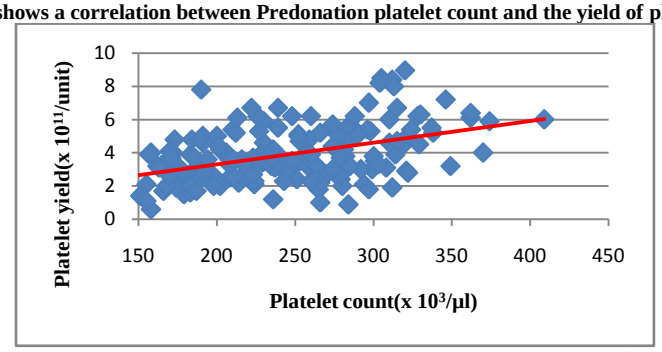
Parameters	Pre-donation (mean ± SD) Range	Post-donation (mean ± SD) range	Decrease (-)/ increase (+) (%)	(p- value)
Hb (g/dl)	15.3 ± 1.2 (11.2-18.4)	15.6 ± 1.3 (12.2-18.8)	+ 0.27 (1.7%)	0.000
Hct	42.7 ± 3.4 (32.5-53)	43.4 ± 3.6 (34.9-53.5)	+ 0.65 (1.5%)	0.000
Platelet count (x 10^3/µl)	241 ± 149 (149-409)	170 ± 48 (90-342)	- 74 (30%)	0.000
MPV (fl)	10 ± 7.3 (7.3-14.5)	9.8 ± 1.3 (7-14)	0.07 (0.7%)	0.116
PDW	37.3 ± 25 (25-46)	37 ± 2.6 (29.1-42.8)	0.3 (0.8%)	0.500

Table 2 shows correlation between predonation platelet count and the yield of platelets. The mean platelet yield of all procedures was 3.8± 1.65 X 10^{11} /unit. Figure 1 shows a direct correlation between predonation platelet count and the platelet yield ($r = 0.446$, $p < 0.001$). The platelet count was > 3x 10^{11} in 83% of procedures.

Table 2: Effect of pre-donation platelet count on platelet yield (mean and range)

Pre-donation platelet count (x 10^3/µl)	Number of donors	Mean platelet yield ± SD	Minimum yield	Maximum yield
< 200	46	3.026 ± 1.32	0.6	7.8
200-300	93	3.781 ± 1.38	0.9	7.0
> 300	32	5.379 ± 1.87	1.9	9.0
Total	171	3.869 ± 1.65	0.6	9.0

Fig.1 shows a correlation between Predonation platelet count and the yield of platelets



Platelet yield was negatively correlated with MPV ($r = - 0.447$) and PDW ($r = - 0.396$) and was not found to be statistically significant as shown in Figure 2 and Figure 3 respectively. Figure 4 shows that there was no significant correlation of Platelet yield with predonation Hb ($r =- 0.004$, $p = 0.954$). Similarly, multiple linear regression analysis demonstrated no effect of donor age and weight on platelet yield.

Fig2. Correlation of MPV with platelet yield

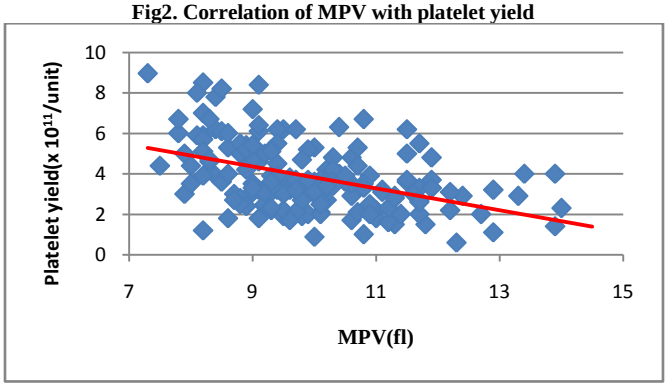


Fig 3. Correlation of PDW with platelet yield

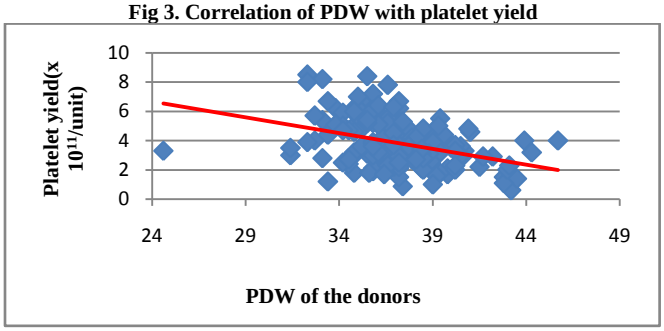
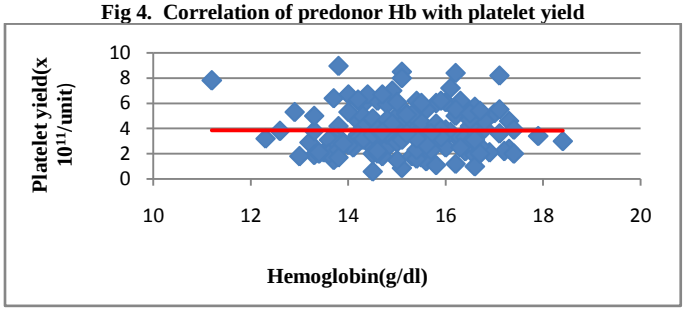


Fig 4. Correlation of predonor Hb with platelet yield



4. Discussion

Plateletpheresis is becoming a routine procedure in most of blood centres in developing countries. There have been significant improvements in productivity and quality of apheresis platelets. However, donor safety issues with regards to reduction in hematological values have received little attention. The present study addressed the changes in hematological parameters after plateletpheresis and influence of donor hematological parameters on the platelet yield.

On evaluation of donor related parameters on platelet yield, we found that predonation platelet count has significant linear correlation with the platelet yield ($r = 0.446$, $p < 0.001$). The higher the platelet count means more platelets are available for collection. Out of the 171 donors assessed for pre-donation platelet count effect on platelet yield, 46 (26%) had a pre-donation platelet count < 200 x 10^3/µl. The mean yield of product prepared from these donors was 3 x 10^{11}/unit. 93 donors had a pre-donation count in the range of 200-300 x 10^3/µl and the mean yield in the product from these donors was 3.7 x 10^{11}/unit. 32 donors had pre-donation counts > 300 x 10^3/µl and the mean yield in the products prepared was 5.3 x 10^{11}/unit.

Chaudhary *et al* in a study of 94 plateletpheresis procedures found a mean yield of 2.8 ± 0.73 x 10^{11}/unit and they found that when the pre-donation platelet count was greater than 300 x 10^3/µl, the yield was greater than 3 x 10^{11} platelets/unit in 80% of the products. They also reported that the mean yield was 2.5 ± 0.59 x 10^{11}/unit when the pre-donation platelet count was < 200 x 10^3/µl[9]. Our results were in accordance with these observations and the platelet yield correlated linearly with the pre-donation platelet count of the donor

Goodnough *et al* studied 708 plateletpheresis procedures and a direct correlation between platelet yield and pre-donation platelet count was observed in all the procedures. In 12% of the procedures, the mean yield was < 3 x 10^{11}/unit when the pre-donation platelet count was < 200 x 10^3/µl[4]. Many other studies have also demonstrated significant positive correlation between the donor platelet count and the yield of the product[10-12].

According to the AABB requirements[13], 75% of the plateletpheresis products prepared must contain ≥ 3 x 10^{11} platelets per unit, while the European guidelines (Council of Europe publishing, 2006) recommend platelet count of ≥ 2 x 10^{11}/unit[14]. These levels have been determined from the studies to provide required haemostatic dose to the recipient. 129 (76%) numbers of procedures in our study have platelet yield of > 3x 10^{11}/unit.

We observed negative correlation between the donor Hb and platelet yield ($r = - 0.004$) and it was statistically insignificant ($p = 0.954$). Other authors also reported no correlation between pre-donation Hb and the yield[15, 16]. Chaudhary *et al* found no correlation between the pre-donation Hb and the yield ($r = - 0.10$, $p > 0.005$), but in three donors with Hb > 16 g/dl gave a lower yield as compared with donors having Hb < 16g/dl[9]. In contrast, an inverse relationship between the Hb and the yield has been demonstrated by Guerrero-Rivera *et al* and Enien *et al*[6, 17]. They concluded that this might be related to the greater amount of plasma processed in donors with low Hb.

We also studied the effect of donor MPV on platelet yield. In our study, we found a direct negative correlation between the mean MPV of the donor and the platelet yield obtained ($r = - 0.447$, $p < 0.001$). 51 (29%) of donors had MPV in the range of 7-9 fl and the mean platelet yield in these donors was 4.9 ± 1.7 x 10^{11}/unit. Maximum number of donors (49%) had MPV in the range of 9-11fl and the mean platelet yield obtained in this range was 3.5 ± 1.4 x 10^{11}/unit. 30 (17%) donors had MPV in the range of 11-13 fl and the mean yield obtained in this group was 2.95 ± 1.2 x 10^{11}/unit. Hence, it was observed that higher MPV values corresponded to lower platelet yield. This could be explained on the basis of separation mechanism of the Amicus. The separation of platelets by automated cell separators like Amicus is based on cell size. As the size of platelets increase, these large platelets are excluded from collection mimicking as red cells. Hence, the smaller platelets are collected more efficiently by the machine and hence yielding a better product.

Although we expect a decrease in hematological values after plateletpheresis procedure, adverse clinical outcomes, such as thrombocytopenia and anemia as a result of these decreases should be prevented. In our study, the mean pre-donation platelet count of the donors was 241 ± 57.1 x 10^3/µl with a range of 149 - 409 x 10^3/µl. The mean post-donation platelet count was 170.2 ± 48.8 x 10^3/µl. We found that the post-donation platelet count showed a significant decrease in all of the procedures ($p < 0.001$). The mean decrease in the post-donation platelet count was 74.0 ± 36.6 x 10^3/µl (30.7%). The post-donation platelet count was less than 100 x 10^3/µl in 4 procedures, fortunately with no clinical manifestations. Significant reductions in platelet count after plateletpheresis have also been reported by other researchers [18, 19]. Lazarus *et al* did not find any donors with clinical thrombocytopenia among 939 donors who underwent 11,464 procedures [20].

After plateletpheresis procedure, we observed 1.7% increase in post donation Hb values and was statistically significant ($p <0.001$). This might be due to the fact that concentrated red cells were returned to the donor and 200-300 ml of plasma was retained at the end of the procedure. The increase in Hb may be apparent as the sample was withdrawn immediately after the procedure. Love *et al* reported an increase in Hb and hct after plateletpheresis[18]. Other studies demonstrated conflicting results i.e. decrease in Hb and hct [15, 21]. This could be explained on the basis that there was a time-lag between the end of procedure and obtaining sample which allowed physiological mechanisms to come into action. Another factor causing variation in results may be the

cell separator used. Taking into account the above observations, post-donation changes in the donors should be reviewed in those donors whose hematological parameters are border-line or who undergo frequent plateletpheresis.

We observed post-procedure change in donors MPV and PDW. The post-donation decrease in the MPV was 0.0752 (0.7%) which was not statistically significant ($p = 0.116$). The post-donation decrease in PDW was 0.115 (0.3%) which was not statistically significant ($p > 0.500$). Das *et al* conducted a study on a total of 477 plateletpheresis procedures using five different cell separators over a period of 26 months. It was observed that there was no significant change in MPV or PDW of the donor after each procedure ($p > 0.5$)[15].

On evaluating the effect of donor clinical variables such as age and weight on yield, there was no significant correlation ($r = 0.067$, $p > 0.01$). Chaudhary *et al* also studied the effect of donor weight on platelet yield and did not find any significant correlation[9]. Buchholz *et al* studied the quality of SDP in relation to low weight of the donors and demonstrated no effect of donor weight on platelet yield[22].

There were certain limitations in our study. The donor sample was obtained soon after completion of the procedure. Hence, the change in the hematologic values observed may not be representative of changes taking place over a longer time period (1 or 2 days). In addition, in our study, biochemical parameters were not considered at all and it is possible that post procedure, there could be biochemical changes which have not been looked into. These issues are more important in determining the suitability of frequent plateletpheresis donors. The 1990 UK guidelines recommend that frequent apheresis donors should be assessed for blood counts, total protein and albumin [23]. Also, since double dose platelet collections (collection of two units from a single donor) were not performed in any of our cases, we could not address issues regarding donor safety and quality of products in these settings. The Drugs and Cosmetics Act, which is regulatory body in blood transfusion services in India, should establish guidelines for repeat plateletpheresis donors [24].

There is a need that all transfusion centers should have their own plateletpheresis donor data based on demographic and hematological characteristics of the donor population. This will ensure donor safety, product quality and an effective donor registry. More prospective studies are required to establish guidelines for donor safety in apheresis, especially in the present trend of double dose platelet collections.

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