A Study of Effect of Different Donor Parameters on single donor platelet apheresis in central India Tertiary care hospital

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Abstract
Introduction: Use of single donor platelets (SDP) has increased by radical change over past few years. SDP not only increase the quality of product in terms of decreased cellular contamination but also increases the overall yield of platelet collected. However various donor parameter exert their effect on yield of single donor platelet apheresis.

Materials and Methods: The present study included the outcome of 65 SDPA procedures that were conducted on Haemonetics MCS+ intermittent flow cell separator (Haemontetic Corporation). It employs single venous access utilizing closed collection apheresis kits with efficient leukoreduction. Study was undertaken at blood bank M.Y. Hospital associated with M.G.M. Medical College, Indore, and a tertiary care Central Government Teaching Institute.

Results: The mean platelet yield was 2.7±0.83(1.6-4.9 × 10¹¹/µl). Platelet yield showed high statistical significance with pre donation platelet count (p =0.000). Other than pre donation platelet counts, SDP yield also showed statistical significant correlation with weight and MPV. However no statistical significance was seen height (p=0.838), Hemoglobin (p=0.554) pre donation WBC count (p=0.052) and PDW (p=0.963) of donor on platelet yield.

Conclusion: Hence, in our study, we found platelet yield showed positive statistical significance with pre donation platelet count as well as with pre donation weight and MPV. To find out interventions that could increase pre donation platelet would have a positive effect on platelet product yields

Keywords: Apheresis, Platelet yield, Single donor platelet (SDP), Parameters.

Introduction
Apheresis in greek (apairesos) literally means to take away¹¹. Use of single donor platelets (SDP) has increased by radical change over past few years. SDP not only increase the quality of product in terms of decreased cellular contamination but also increases the overall yield of platelet collected. However various donor parameter exert their effect on yield of single donor platelet apheresis. Single donor platelet apheresis is a
method of collecting platelets, a component of blood involved in blood clotting, which is performed by a device used in blood donation that separates the platelets and returns other components of blood to the donor. Compared to whole blood donation, apheresis has some advantages for the donor, including a lower red blood cells loss, which means that even females with low haemoglobin values could undergo apheresis.

According to AABB guidelines apheresis platelets require to have a product count of more than 3x10^{11} platelets / bag in at least 90% of the products, whereas the 2007 council of Europe recommends >2x10^{11} platelets per haemostatic dose of SDP[2]. Donor can donate platelets at a minimum interval of 48 hours, not more than twice a week and not more than 24 times a year. AABB standards donot require a pre platelet count for single and double apheresis platelet collections. SDPA carry additional benefits of lowered risk of exposure to transfusion transmitted infections (when compared to pooled platelets), all immunization and febrile non haemolytic transfusionre actions particularly in multi transfused aplastic anaemia or cancer patients. This in turn is influenced by quality of platelet product particularly in terms of yield[3]

Donor related factors namely age, sex, weight, height, haemoglobin (Hb), total leukocyte count (TLC), haematocrit and platelet count, platelet indices -Mean platelet volume (MPV), Platelet deviation width (PDW) have been thought to influence platelet yield. Out of these donor parameters, pre donation platelet count is considered most important.

With increased demand for apheresis platelets, higher platelet yield and higher donation frequencies were followed to meet the demand. This practice has raised concern on donor platelet depletion. The effects of apheresis donation on donor haematological parameters have been studied more in the west. There remains a conflicting picture on the effect of platelet apheresis on the donor with some studies concluding even repeated platelet apheresis is safe with no significant adverse effects[4] and some reporting significant effect on haematopoiesis[5].

**Materials and Methods**

The present study included the outcome of 65 SDPA procedures that were conducted on Haemonetics MCS+ intermittent flow cell separator (Haemonetic Corporation). It employs single venous access utilizing closed collection apheresis kits with efficient leuko reduction. Study was undertaken at blood bank M.Y. Hospital associated with M.G.M. Medical College, Indore, and a tertiary care Central Government Teaching Institute. Donor undergoing an occasional apheresis procedure must meet the same criteria as a whole blood donation as per Director General Health Services guidelines.[6]

1. Age 18-60 years
2. Platelet count greater than or equal to150-200 × 10^{9} /L
3. Haemoglobin levels greater than or equal to 12.5 g/dl and donor body weight greater than or equal to 60 kg
4. No consumption of non-steroidal anti-inflammatory drugs and acetyl salicylic acid in the last 3 days with absence of any illness
5. Time lapse of at least 3 months since last whole blood donation and time lapse of at least 3 days since last platelet pheresis donation.
6. Adequate venous access
7. Written informed consent will be obtained before the procedure.
8. Tests for Haemoglobin, ABO Rh and TTI (Human immunodeficiency virus (HIV) 1, 2 antibodies and hepatitis B surface antigen, hepatitis C antibody, malaria and syphilis).

Donors who were motivated to donate by apheresis method were requested to fill the donor questionnaire form. Donors were subjected for clinical examination. Haemoglobin was measured by sysmex kx21 hematology analyser. Blood pressure and pulse rate were recorded. Blood sample from donor was sent for platelet count estimation by cell counter to haematology department.
laboratory. Blood grouping and Rh typing were done. Screening for Transfusion Transmissible Infections on the donors and on the product were done using third and fourth generation ELISA, and the procedures were performed stringently as per standard operating procedures (SOP’s) of the department. Blood flow rate for all platelet pheresis were maintained at 45– 90 ml/min with anticoagulant (ACD-A) ratio of 12:1. At least 1% of all apheresis units underwent quality control. Though the machine calculated the platelet yield of SDP unit. It was also confirmed manually. To calculate the yield as well as to run the quality control, approximately 1 ml sample from each bag was collected in EDTA (K2 EDTA) following stripping of the tube segment. The samples were allowed to be mixed thoroughly over a mechanized blood mixer for quarter of an hour and then evaluated by Sysmex KX 21 haematology analyser. Platelet content and cellular contaminants were determined. Before each procedure was undertaken, samples from donor were similarly evaluated for haemoglobin (Hb), total leukocyte count (TLC), haematocrit and platelet indices (count, MPV, PDW). Other donor variables such as age, gender, weight and height were also documented for analysis. The various factors possibly affecting platelet yield were studied using chi-square test and calculating p value using SPSS software version 20.0 for Windows.

**Results**

The age and haematological parameters of healthy donors is enlisted in [Table/Fig-1].

From 65 donors, there were 63 (96.92%) male donors and 2 (3.07%) female donors. The mean platelet count was 272.0± 58.0 per/µl which was higher in females than in males. Men had significantly higher pre donation haemoglobin (15.39± 1.40) than in women (12.9 ± 0.56 gm %). The mean values of pre donation haemoglobin was 15.31±1.45gm/dl. The mean platelet yield was 2.7± 0.83 (1.6-4.9 × 1011/µl). Platelet yield showed high statistical significance with pre donation platelet count (p =0.000) The pre donation platelets were divided into 4 groups ( group 1:150-200× 10³/µl , group 2: 200-250 × 10³/µl , group 3- 250-300 ×10³/µl and group4-> 300x10³/µl). Out of 225/ 57 donors fell in group 1, 70 in group 2, 59 in group 3 and 39 in group 4 as shown in [Table/Fig-2]. The yield ≥ 3 × 10¹¹/µl was seen in 00/03 (00.0%) group 1, 8/26 (30.7 %) in group 2, 08/11 (42.1%) in group 3 and 13/17 (76.5%) in group 4. Hence the platelet yield progressively increased from group 1 to group 4 [Table/Fig-2]. Other than pre donation platelet counts, SDP yield also showed statistical significant correlation with weight and MPV.

However no statistical significance was seen height (p=0.838), Hemoglobin (p=0.554) pre donation WBC count (p=0.052) and PDW (p=0.963) of donor on platelet yield.

**Discussion**

Use of single donor platelets (SDP) has increased by radical change over past few years. SDP not
only increase the quality of product in terms of decreased cellular contamination but also increases the overall yield of platelet collected. There are few studies in literature that study the effect of these variables on platelet yield, in a developing country like ours. To optimize the yield of apheresis products donors should be selected according to Director General of health services (DGHS) guidelines for apheresis.

Goodnough et al., studied 708 platelet pheresis procedures performed on 533 donors having mean pre-donation platelet count of $237 \pm 49 \times 10^3/\mu l$ which resulted in platelet product with mean yield of $4.24\pm1.1 \times 10^{11}$. A direct linear correlation was observed with all the procedures\[7\].

Das SS et al studied 61 platelet pheresis procedures. Pearson correlation of 61 procedures indicated good direct linear correlation between pre-donation platelet count and yield for all procedures ($r = 0.51$, $p < 0.001$)\[8\].

A direct positive relationship was observed between pre-donation platelet count and yield ($r = 0.50$, $p < 0.001$) by Chaudhary R et al.,\[9\]. A direct positive relationship was observed between pre-donation platelet count and yield ($p < 0.001$) by Shalini Bahadur et al.,\[10\]. In our study, mean pre-donation platelet count was $272.0\pm 58.0$ per $\mu l$ which resulted in platelet product with yield of $2.7\pm 0.83 \times 10^{11}$. Results of present study were also in coincide with other studies and found a statistically significant positive correlation between the platelet yield and pre-donation platelet count ($p<0.001$).

However in contrast to earlier studies we divided the pre donation platelet count into 4 groups and found that yields was highest with group 4 closely followed by group 3 with a progressively increasing trend seen from group 1 to group 4.

According to the American Association of Blood Banks (AABB) \[11\] 75% of the SDP must contain $>3 \times 10^{11}$/unit while the European guidelines \[12\] recommend a platelet count $>2 \times 10^{11}$/unit. Our blood bank follows guidelines laid down by Drugs Controller of India which are largely based on American Association of Blood Banks (AABB) standards in this respect\[13\].

Out of 65, 29 (44.61 %) of our SDP’s met the AABB criteria. 36 (55.38 %) of our SDP’s had platelets $< 3 \times 10^{11}$/unit.3/36 (8.33%) of these SDP’s had pre donation platelet count between 150-200 $\times 10^7$ $\mu l$. Similar results were shown by Chaudhary et al., in 2006 with a yield of $>3 \times 10^{11}$/unit in SDP with the pre donation platelet count $>300 \times 10^3/ \mu l$\[9\]. Study by Goodnough et al.,\[7\] and Hester et al.,\[14\] also showed similar results.

No significant correlation was observed between age, height and Haemoglobin on platelet yield. ($p > 0.005$) Similar results were seen by Buchholz et al\[15\] and Chaudhary et al.,\[9\]. Significant positive correlation between the platelet yield and weight ($p<0.001$).

**Conclusion**

Hence, in our study, we found platelet yield showed positive statistical significance with pre donation platelet count as well as with pre donation weight and MPV. The technical advancement of apheresis machine and therapeutic interventions will in time increase the ability of blood banks to provide good quality SDP. To find out interventions that could increase pre donation platelet would have a positive effect on platelet product yields and ultimately leading to better platelet recovery in the recipient.

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