ORIGINAL RESEARCH PAPER

Immunohematology

KEY WORDS: Plataeletpheresis; Hematocrit; Hemoglobin; Platelet Count; Thrombocytopenia; Venepuncture.

COMPARISON OF PRE AND POST PLATELETPHERESIS VALUES OF HEMOGLOBIN, HEMATOCRIT AND PLATELET COUNT IN HEALTHY DONORS.

Mitali Sharma Senior ResidentDepartment of Blood Transfusion and Immunohematology, GMC JAMMU.

Vijay Sawhney* Professor and HOD ,Department of Blood Transfusion and Immunohematology, GMC JAMMU. *Corresponding Author

Ankur Malhotra Senior ResidentDepartment of Blood Transfusion and Immunohematology, GMC JAMMU.

ABSTRACT

INTRODUCTION: Now a days, the cell separators can yield high dose plateletpheresis, resulting in up to four units of apheresis platelets for transfusion to patients. However, concerns regarding the safety of platelet donors run contrary to these interests and technical possibilities. This can be easily investigated by measuring the Hb , Hct and total platelet counts, of normal donors before and after plateletpheresis. As these hematological changes may induce clinical implications to the donor such as anaemia and thrombocytopenia.

AIM: To compare the pre and post plateletpheresis values of Haemoglobin , Haematocrit and platelet count in healthy voluntary donors.

MATERIAL AND METHOD: The study was conducted on 57 healthy, plateletpheresis donors over a period of one year. The plateletpheresis procedures were performed using COM.TEC,FRESENIUS Kabi apheresis machine with closed system apheresis kit various pre- and post-donation haematological values such as haemoglobin concentration (Hb), haematocrit (Hct)and platelet counts, were measured in all donors.

RESULTS: We observed that the Hb, Hct,and platelet counts decreased significantly in the donors ($p<0.01$) after each procedure.

CONCLUSION: Although a significant drop in Hb, HCT and platelet count was observed in all donors, none manifested features of anaemia and /or thrombocytopenia. Changes were within normal range and did not lead to any significant adverse effects on the donor. In conclusion, it can be said that, plateletpheresis is a safe procedure for healthy donors.

Plateletpheresis is a procedure where the whole blood is processed from a donor and the platelets alone are separated and the remaining blood components are returned back to the donor [17].

The intravascular volume deficit during the procedure should not exceed 10.5 mL/kilogram of the donor's weight. Plateletpheresis units must contain 3.0 $X10^{11}$ or more platelets per unit in at least 75% of the units tested at maximal storage time. The physician in charge of the donor apheresis unit can make a medical decision to accept a donation from someone not eligible at the time if the benefits to the intended recipient outweigh the risks to the donor.[13]

Now a days, the cell separators can yield high dose plateletpheresis, resulting in up to four units of apheresis platelets for transfusion to patients. However, concerns regarding the safety of platelet donors run contrary to these interests and technical possibilities. This can be easily investigated by measuring the total platelet counts of normal donors before and after plateletpheresis. As these hematological changes may induce clinical implications to the donor such as thrombocytopenia. Plateletpheresis is used to obtain large numbers of platelets from random volunteer donors. One unit of plateletapheresis is equal to 4 to 6 random donor platelets.[11]

Transient but significant decreases in platelet counts have been documented to occur in donors undergoing single and serial short-term plateletpheresis collections[7].

The changes in the post-donation haematological parameters should be evaluated so that the effect on the donor health can be assessed. The 2005 United Kingdom Guideline for Blood Transfusion Services recommends analysis of complete blood count at least on yearly basis for plateletpheresis donors. However the Indian Drug and Cosmetic Act (1940) has not yet established any guideline for this.

The post-donation platelet count, haemoglobin, haematocrit and total leucocyte count have shown significant changes. Some studies have reported an increase in post-donation haemoglobin ,haematocrit and TLC [8] while others have described a fall in these parameters after donation. As the data is conflicting, we planned to study the changes in these parameters in our setup. Although many undergo plateletpheresis but the data on consequences of plateletpheresis for donor's health is limited. The aim of this study is to determine the effects on Hb, Haematocrit and platelet count in healthy donors after plateletpheresis.

MATERIALS AND METHOD

The study was conducted in The Department of Blood Transfusion and Immunohaematology, Government medical college, Jammu. This is a tertiary care centre attending to needs of people of Jammu and adjoining area of Punjab and Himachal Pradesh. The study was carried out between December 2015 to November 2016, over a period of 1 year. Ethical clearance for undertaking the present study was obtained from Ethical Committee of our Hospital at the time of submission of Plan of Thesis.

The study was conducted on all the plateletpheresis, fulfilling the below mentioned criteria:

Donor selection criteria for blood donation included(Saran 2003)- Donor should be in good health, physically fit and mentally alert, age group 18-60 years, weight >45Kg, Haemoglobin >12.5g/dl., Haematocrit >38%, Body temperature was not >37.5 C, The site of venipuncture was free of any skin lesions, pulse was regular and frequency was between 60- 90 beats/min and blood pressure <160 mmHg systolic and <100 mm Hg diastolic Some other specific donor selection criteria for plateletpheresis included:

1. Platelet count >150x 10^9 cells/L
2. Negative serological marker for HIV 1&2, HBsAg, HCV, VDRL & Malaria
3. In the present study ABO&Rh compatible donors were selected for Plateletpheresis.
4. Minimum 8 weeks interval between whole blood donation and subsequent Plateletpheresis.
5. If it became impossible to return the donor's red cells during Plateletpheresis then atleast 8 weeks were allowed to elapsed before a subsequent Plateletpheresis was done unless the extracorporeal red cell volume was less than 100ml
6. Minimum interval between two Plateletpheresis donation was atleast 48 hrs. a donor was not allowed to undergo the procedure more than 2 times in a week or 24 times in a year

- The donors with the history of the Ingestion of Aspirin containing medication within 36 hrs of donation, Jaundice or viral Hepatitis (past 1 year), Respiratory infections, Tuberculosis, Heart ailment, Fever or infectious disease, history of any recent vaccination, Surgery with in past 6 months, Pregnancy, Syphilis (within 12 months of treatment) and Malignancies etc were excluded from our study.

MATERIALS:

- SOP
- IEC material
- COM.TEC,FRESENIUS Kabi apheresis machine with closed system apheresis kit
- Donor Questionnaire form
- Consent form of the donor
- Requisition form filled by treating consultant
- Weighing machine
- Hemocue
- Automated Haematology cell Counter (Abott &Beckmann)
- Serological kits for HIV, HbsAg, HCV, VDRL, and Malaria.
- Potassium EDTA Vacutainer
- Sodium citrate vials
- Platelet agitator incubator
- Label for the bags
- Binocular microscope

METHOD:

A. Pre-donation activities:

- Written consent for the plateletpheresis procedure by the treating consultant were checked
- Donor questionnaires were filled up and answered by the donors.
- The age and weight of the donors were noted
- Medical examination of the donors was done
- The donors were checked for good venous access in both arms and the arm with better venous access was chosen for the procedure.
- Written Consent of the donors were taken after explaining the procedure to the donors in the language understood by them.
- The sample for pre-donation haemoglobin, haematocrit and platelet count were taken in EDTA vacutainer about 3ml in amount. These tests were be done on the Automated Haematology Cell Counter. ABO-Rh grouping were done by tube technique.
- Screening for Transfusion Transmitted diseases were done for HIV, HbsAg, VDRL, HCV, Malaria using rapid kits

B. Activities related to Donors;

- The donors were encouraged to drink some water and loosen tight clothing and lie comfortably.

C. Procedure:

- Physical inspection of the apheresis kit was done.
- Expiry of the bag, saline and anticoagulant were checked
- Then loading of kit was done on the machine
- The kits were checked for kinks or wrong intall .The machine was then primed.
- Donor phlebotomies were done using standard guideline as written in the SOP

Plateletpheresis were done using COM. TEC, FRESENIUS Kabi apheresis machine using PLT-5d-SN Program with S5L sets which are closed system permitting the storage of platelets for up to 5 days. It is an intermittent flow centrifugation machine and requires one venepuncture site. Acid-citrate-dextrose formula A (ACD-A) was used as anticoagulant during procedures according to the manufacture's recommendations. The procedures were performed under all aseptic conditions. The machine has default ACD rate of 1.2ml/min/L and the ACD: Blood ratio of 1:9 for a donor with haematocrit of 40%.

- Donor monitoring (pulse, respiration, any discofort) was done during the procedure.
- Documentation of the procedure was also done.

D. Post-donation activities include:

- Examination of the vitals e.g. BP, pulse, Respiration.
- Any discomfort to the donor during the procedure was documented

a. The post-donation samples were taken from the donors immediately after the procedure as soon as the donors are disconnected from the Apheresis machine. About 3ml in EDTA vacutainer for Hb, Hct, and platelet count.
b. The Hb, Hct and platelet count values were determined using Automatic Haematological cell counter.

.

After the procedures were complete the bags were kept at room temperature for 1 hour and then were stored in the Platelet Agitator Incubator. Visual check of the products was done before issuance.

STATISTICAL ANALYSIS

All the observations were charted in MS Excel sheet and statistical analysis was done. The data was expressed as mean± SD. The mean pre-donation and post-donation values of the donor haematological and coagulation parameters were compared using **paired student t test**. A p value <0.05 was taken as significant.

RESULTS

A total of 57 plateletpheresis procedures were performed in the period of One year study period. Plateletpheresis procedures were done on Fresenius Kabi COM.TEC Apheresis machine using closed system apheresis kits. All donors were males in our study and no female underwent plateletpheresis during this period. The mean pulse rate was 75.40± 7.97 beats/min and mean B.P 120.25/79.23± 6.97/5.78mmHg. The mean volume of platelet product was 202.37 ±9.45 ml. Only the donors fulfilling the donor criteria strictly were included in the study.

All the post-donation donor haematological parameters showed a significant decrease from the pre-donation values ($p<0.001$) (table -2). The mean post-donation Haemoglobin observed was 12.84 ±0.98g/dl while the pre-donation mean Haemoglobin recorded was 13.98±0.96 g/dl . The range of post-donation Haemoglobin was 10.5 -15 g/dl as compared to pre-donation range of 12.5-16.3 g/dl. The decrease in Hb was 8.15% and was significant ($p<0.001$)(Figure 1).

The post-donation Haematocrit showed a mean of 39.72 ±2.84% with a range 33.2-47.5% of while the pre-donation Haematocrit had a mean of 42.71± 3.02% with range of 38-51%. Hence a significant decrease (7.02%; $p<0.001$) in the haematocrit was noted.(figure 2)

As depicted in table-1 ,the post-donation platelet count showed a mean of 165.67±61.88X10^9/L where as the pre-donation platelet count recorded was 221.53± 51.95 X10^9/L. It was thus observed that decline in the post-donation platelet count was significant ($p<0.001$) with decrease of 25.21%.(figure 3)

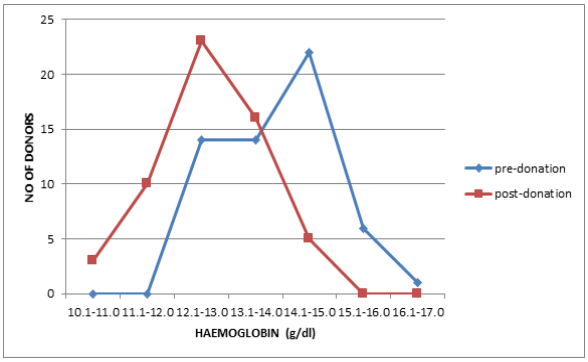

FIGURE 1: Comparison between pre and post-donationha emoglobin values

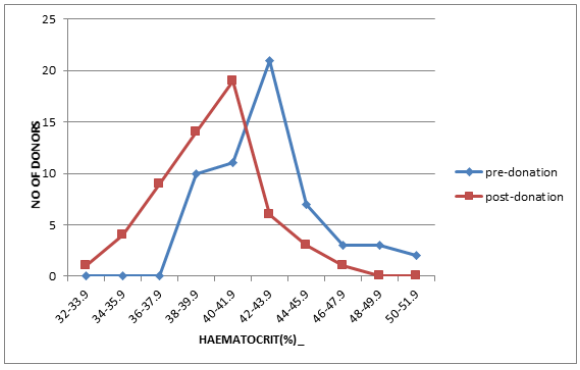

Figure 2:Comparison between pre and post-donation haematocrit values

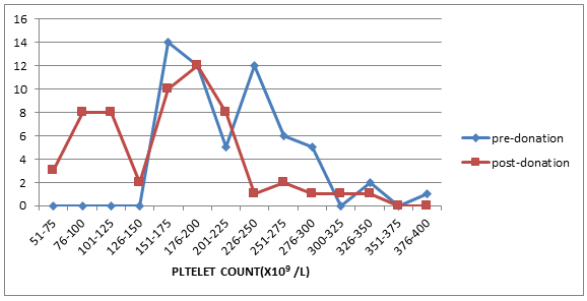

FIGURE 3:Comparison between pre and post-donation platelet count values

TABLE 1: Comparisons Of Pre And Post-donation Mean, Upper Limits And Lower Limits

PARAMETER	PRE-DONATION			POST-DONATION		
	Mean	Upper limit	Lower limit	Mean	Upper limit	Lower limit
HAEMOGLOBIN (in gm/dl)	13.98	16.3	12.5	12.84	15	10.5
HAEMATOCRIT (%)	42.71	51	38	39.72	47.5	33.2
PLATELET COUNT ($X10^9$/L)	221.53	387	151	165.67	350	74

TABLE 2: post-donation Changes In Donor Parameters

VARIABLES	PRE-DONATION VALUE (Mean ±SD)	POST-DONATION VALUE (Mean ±SD)	CHANGE (%)	STATISTICAL SIGNIFICANCE
HAEMOGLOBIN (in gm/dl)	13.98±0.96	12.84 ±0.98	-8.15	<0.001 t= 6.27
HAEMATOCRIT (%)	42.71± 3.02	39.72 ±2.84	-7.02	<0.001 t= 5.45
PLATELET COUNT ($X10^9$/L)	221.53± 51.95	165.67 ±61.88	-25.21	<0.001 T=5.22

DISCUSSION:

In the present one year study conducted in the Department of Blood Transfusion and Immunohaematology, GMC Jammu, 57 donors underwent plateletpheresis procedure on the machine FRESENIUS Kabi COM.TEC using a closed system with one venepuncture site. The values of various donor parameters i.e. Haemoglobin, Haematocrit and Platelet count were recorded before and after plateletpheresis and they were compared and assessed.

- In our study on 57 donors the **post-donation Haemoglobin** showed a mean of **12.84±0.98g/dl** where as the mean pre-donation Haemoglobin was found to be **13.98±0.96g/dl.** The decrease in Haemoglobin was found to be 8.15**%** and was found to be statistically significant **(p<0.001)**. Post-donation Haemoglobin less than 12g/dl, which is defined by WHO as anaemia irrespective of the gender occurred in **12 cases (21.05%)** out of 57 donors. Out of these 12 donors, **10 (83.33%)** donors with **post-donation Haemoglobin <12g/dl** pre-donation had Haemoglobin between 12.5-12.9g/dl. Only 2 donors with pre-donation Haemoglobin equal or >13g/dl had post-donation Haemoglobin <12g/dl. Therefore, we can conclude that taking into consideration the fact that 21.05% of our donors had post-donation Haemoglobin <12g/dl and that this finding was seen in 83.33% of the donors with pre-donation Haemoglobin <13g/dl, we should have a policy of examining such donors for post-donation decrements.

Das et al **.** Reported that after plateletpheresis, 8.1% of the donors had a post-donation Hb concentration of <12 g/dL. Moreover, the Hb value fell to below 10.8 g/dL in two female donors after the procedure. Both these donors failed to revisit the apheresis centre due to lack of finance and time[4,5].

Akay et al also reported a decrease in the post- donation Haemoglobin from 15.0±0.4g/dl to 14.4±0.4g/dl.[2]

The decrease in the post-donation Haemoglobin values could be a result of the dilutional effect of the anticoagulant and saline that is reinfused in the donor Suresh et al compared the pre and post-plateletpheresis haematological values. Following plateletpheresis a significant decrease in pre- and post-donation Hb (g/dL) (14.8 ± 1.097 Vs 14.5 ± 1.4; p=0.002); haematocrit (%) (43.29 ± 6.62 Vs 41.64 ± 4.96; p=0.045) was reported.[17]

However, Love et al reported an increase in the post-donation Haemoglobin values both in females as well as males but no definite cause for this finding was elucidated by them[8].

The mean **pre-donation Haematocrit** in our study was **42.71±3.02**% while the mean **post-donation Haematocrit** was found to be **39.72±2.84%.** The difference between pre and post-donation mean Haematocrit showed a decrease **of 7.02%**. The decrease was significant as p value <0.001 was recorded. This decrease could be result of effect of saline and anticoagulant dilution. Several other studies mentioned below have also shown a similar significant decrease in the post-donation Haematocrit.

Rock et al**.** reported a mean pre-donation Haematocrit of 44**±**2% While the mean post-donation Haematocrit was 43**±**2%.[12]

Love et al. , meanwhile, found an increase in the post-donation Haematocrit as compared to the post-donation Haematocrit. The reason for this finding was not elucidated. However, the cell separator they used was Haemonetics PCS and in our study we conducted procedures in Fresenius Kabi COM.TEC.[8]

Beyan *et al.* reported a significant drop of both Hb and Hct with the Fenwal CS 3000 plus and the Fresenius AS-204 machines when compared to the COBE spectra[3]. Patidar et al reported that there was significant post procedure drop in Hb, Hct, and platelet count of the donors ($p < 0.0001$) after plateletpheresis[10].

The change in the donor's platelet count after donation was also analysed. The mean **pre-donation platelet count** in our study was **221.53±51.95 x 10^9 platelets/L**. The mean **post-donation platelet count recorded was 165.67 ±**61.88 **x 10^9 platelets /L**. We also found that the post-donation platelet count showed a significant decrease in almost all the plateletpheresis procedures **(p<0.001).** The mean decrease in the post- donation platelet count in our study was **25.21%.** The post-donation platelet count was less than **100x10^9/L** in 11**(19.3%)** of the procedures and all of these procedures were found to have pre-donation platelet count **<200x10^9/L.**

Hester&Ventura [6] and Simon[14,15] have also reported that there was 34-37% decrease in platelet counts but in women a decrease of 45% was reported.

Lazarus *et al*. did not find any donors with clinical thrombocytopenia among 939 regular donors who underwent 11,464 procedures. They found that significant and sustained decrease in platelet counts of up to 50,000/microlitre occurred and correlated with donation frequency. However, they postulated that the donors are unlikely to suffer any clinical adverse effects as a result of this[7].

Rock et al. studied the effects of repeated plateletpheresis on the platelet count of the donors. They found that the mean pre-donation platelet count after first plateletpheresis procedure was 225**±53x**10^9 /L and mean post-donation platelet count was 152**±**32 x10^9/L. The lowest post-donation platelet count was observed at the third donation[12].

Strasser et al reported a platelet count decrease of 27.1**±**7.7% post-donation by using the, machine AS TEC 204 while a decrease of 26.0**±** 12.9% was reported with COBE Spectra [16].

Nadiah AKS et al. reported significant reduction of platelet count among plateletpheresis donors from 294.2 × 109/L to 226.3 × 109/L ($p < 0.05$). From this study, it was found that regular plateletpheresis donor develop sustained decreases in platelet count. These findings have also been reported by other researchers. It was found that the donors should be screened with at least complete blood count before the procedure to ensure that the platelet does not fall below the normal.[9]

There was significaxnt reduction of platelet count among plateletpheresis donors, perhaps beside collection of platelets; it might also due to adhesion of platelet to tubing or centrifuge bowl. About 25–50% of circulating platelets might be lost during single plateletpheresis but this is usually normalized by the spleen, therefore significant thrombocytopenia is not observed in plateletpheresis donors. Hence, the clinical findings of thrombocytopenia are unusual. These findings have also been reported by other researchers. Hence it becomes even more important that the donors should be screened with at least complete blood count before the procedure to ensure that the platelet does not fall below the normal limit.

CONCLUSION

Although a significant drop in Hb, HCT and platelet count was observed in all donors, none manifested features of anaemia and /or thrombocytopenia. Based on results of this study it is recommended that apheresis donors with low normal pre-procedure Hb (i.e. 12.5-13g/dl) and platelet count (i.e. 150-200 x10^9/L) should be examined for post-donation drops in these hematological parameters. Their ability to serve as repeat donor for plateletpheresis also needs to be assessed carefully so that no adverse effect occurs on their health as a result of this. This study showed significant changes in blood hematological , However changes were within normal range and did not lead to any significant adverse effects on the donor. In conclusion, it can be said that, plateletpheresis is a safe procedure for healthy donors.

REFERENCES

1. AABB technical manual 17 th edition C h a p t e r 7 Blood Component Collection by Apheresis .pg 228-230.
2. Akay, OM, Akin, E, Mutlu, F & Gulbas, Z. The effects of plateletpheresis on donor platelet function and coagulation. Trans Apher Sci 2007; 3:113-14
3. 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.
4. 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
5. DAS SS, Chaudhary RK & Shukla JS. Factors influencing yield of plateletpheresis using intermittent flow cell separator. Clin Lab Haematol. 2005; 27: 316–319.
6. Hester JP &Ventura GJ. Modeling of platelet concentrate yield in continuous-flow cell separator devices. J Clin Apher. 1988; 4: 188-93
7. Lazarus EF , Browning J, Norman J, Oblitas J, Leitman SF. Sustained decreases in platelet count associated with multiple, regular plateletpheresis donations. Transfusion. 2001; 41(6):756-61.
8. Love E, Pendry K & Hunt L. Analysis of pre- and post-donation haematological values in plateletpheresis donors. Vox sang 1993;65(3): 209-11.
9. Nadiah AKS, Asiah MN, Syimah ATN et al. Effects of plateletpheresis on blood coagulation parameters in healthy donors at National Blood Centre, Kuala Lumpur, Malaysia. Trans Apher Sci. 2013; 49: 507–10
10. Patidar GK, Sharma RR, Marwaha N .Frequency of adverse events in plateletpheresis donors in regional transfusion centre in North India. Transfus Apher Sci. 2013; 49, (2); 244–248.
11. Rapiaah M; Roshan TM; Naing L, Rehman A; Ahmed SA; Roslin H; Lim SH .The effect of long term donor plateletpheresis on platelet count. Malaysian J Medical Sci; Jan2007 Supplement, Vol. 14, p122.
12. Rock G, Tittley P, Sternbach M, Buskard N & Schroeder M. Repeat plateletpheresis: the effects on the donor and the yield. Vox Sang. 1992; 63(2): 102-6
13. Rossi's Principles of Transfusion Medicine, fourth edition. Chapter 41: Apheresis: Principles and Technology of Hemapheresis. Pg622-624.
14. Simon TL. The collection of platelets by apheresis procedures. Transfusion Medicine Reviews. 1994; 8: 132-45
15. Simon TL, Dzik WH, Snyder EL, Stowell CP & Stauss RG 2002, Rossi Principles of Transfusion Medicine, 3rd Edn, Lippincot William and Wilkin, Baltimore.
16. 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
17. Suresh B, Arun R, Yashovardhan A, Deepthi K, Sreedhar Babu KV, Jothibai DS. Changes in pre-and post-donation haematological parameters in plateletpheresis donors. J Clin Sci Res 2014; 3:85-9.