



Pre-and-post-donation hematological values in healthy donors undergoing plateletpheresis with fresenius.com.tec

Vikas Tiwari¹, Ayush Negi²

¹Professor, Fortis Escort Heart Institute, New Delhi, Delhi

²Student, Fortis Escort Heart Institute, New Delhi, Delhi

ABSTRACT

The present prospective study was carried out in the department of transfusion medicine Forties Escorts Heart Institute, New Delhi from Sep. 2011 to Feb 2012. The study was carried out with the aim to evaluate the effect of automated donation by fresenius.com.tec on the haematological values (HB, PLT count, WBC count, PDW, MPV) pre and post donation and to further evaluate the efficiency of platelet collection by fresenius.com.tec in terms of processing time, platelet yield, type of procedure (SN and DN) and ACD used. A total of 240 donors were subjected for apheresis out of these 229 are male donor and 11 were the female donors and 71 donors were subjected to the donation by SN procedure and 169 underwent donation by DN procedure. Majority of the donor (87%) was between the age group 18-40 years very few donors were (13%) observed between the age group of 41-60 years of age. Total of 240 donors were subjected for apheresis out of them 229 male (95%) donor and very few (5%) are the female donors. A total of 240 donors were subjected for apheresis out of them 71 underwent SN apheresis and 169 were subjected DN apheresis procedure. Majority of the donor (70.42%) underwent DN procedure. The majority of the donors were male in DN (99.41%) and in SN (85.92%) the female donor population was an (0.59%) in DN procedure and (14.08%) in SN procedure as inferred from above data the majority of donor for PHPL were male the percentage of female donor were a little more in SN procedure (14.08%) as compared to DN procedure. The mean platelet count before apheresis was 246 lac/μL with the range of 144-478 lac/μL and the mean platelet count after apheresis 172 lac/μL with the range of 53-367 lac/μL. The mean value of platelet count dropped significantly in post-donation. Similarly the mean Hb level before apheresis was 15 g/dl with the range of 12.5-20.9 g/dl and after apheresis 14 g/dl with the range of 10.2-19.5 g/dl the mean value of Hb dropped marginally in post-donation and the mean WBC count before the apheresis is $8 \times 10^3 / \text{mm}^3$ with the range of $3.9-15.1 \times 10^3 / \text{mm}^3$ and after apheresis it is $7 \times 10^3 / \text{mm}^3$ with the range of $3.8-15 \times 10^3 / \text{mm}^3$. There was no change in PDW and MPV before and after the apheresis. In SN procedure the mean platelet count pre-donation was 241.52 lac/μL with a range of 152-478 lac/μL the mean platelet count post donation was 169.59 lac/μL with a range 71-335 lac/μL the mean platelet count in DN procedure pre-donation was 247.88 lac/μL with range of 144-448 lac/μL and post-donation 173.50 lac/μL with range of 53-367 lac/μL the mean platelet count dropped significantly following apheresis procedure the mean platelet count between either of the procedure was not significantly different. In SN procedure the mean Hb pre-donation was 14.67 g/dl with range of 12.5-18.4 g/dl the mean Hb post donation was 14.7 with range of 10.2 - 18.2 g/dl the mean Hb in DN procedure pre-donation was 15.6 g/dl with range of 12.5 - 20.9 g/dl and in post donation was 14.6 g/dl with range of 12 - 19.5 g/dl the mean Hb dropped significantly following apheresis procedure the mean Hb level in either of procedure was not significantly different. After each procedure, there was no change in WBC count, PDW and MPV. Meantime taken in the procedure performed by SN was 86.48 min and in DN procedure it was 69.12 min. The product yield in SN was 3.10 lac/μL and in DN it was 3.13 lac/μL and the difference of final product count is 8.85 lac/μL in SN and 8.95 lac/μL in DN according to mean values. The product yield, final product count, and time taken by DN procedure were comparatively better than with SN procedure. The volume of ACD used varied from one procedure to another in the procedure performed on fresenius.com.tec it ranged from 220ml to 460ml with the mean of 306 ml. The volume of mean ACD used by SN procedure was 324.87 ml with a range of 210 - 460 ml. The mean ACD volume used in DN procedure was 297.75 ml with a range of (210 - 410ml). The mean ACD volume used was lesser in DN procedure when compared to the SN procedure. The comparison of overall pre-donation means platelet count with mean platelet yield was carried out and student t-test was applied to ascertain the significance of value the p-value of 0.060 was not significant. The overall mean value of various parameter of the present study were analysed and to ascertain the significance of the value the student t-test was applied and out of all the parameter the time taken in the procedure was found to be significant p-value was <0.000 and ACD volume used was also found to be significant were p-value is <0.001. During a total span of six months of study period donation was performed on 240 donors and 35 were temporarily deferred and 09 were permanently deferred for various reasons and the most common cause for donor defer for donation in present study was platelet count below $1.5 \text{ lac}/\mu\text{L}$ (10 deferred), Hb value below 12.5g/dl. On critical analysis of data following facts emerged:- 1. On critical analysis of data that apheresis donor with low normal pre-procedure platelet count $150 - 200 \times 10^9 / \text{L}$ and Hb concentrate 12.5-13 g/dl should be examined for post-donation drops in these haematological parameters. 2. The donor with significant decrements should be reviewed to screen them from a future donor so to avoid iatrogenic anemia and thrombocytopenia. 3. A comprehensive prospective study on this aspect is required to

establish the guidelines for donor safety in apheresis and also in assessing donor suitability. Especially with the double product apheresis collection. 4. This information can be a value an establishing post donation range which could be utilised when reviewing the suitability of donors for subsequent donation. 5. Haematological parameters should be monitored carefully in donor when are undergo long-term regular apheresis.

Keywords— Plateletpheresis

1. INTRODUCTION

Technical advances in automated cell separators have substantially improved the productivity and quality of the collection of apheresis platelets. Various studies on automated plateletpheresis have been conducted to investigate the quality of platelet concentrates and its relation to the biological contribution (platelet count and/or total mass) of the donor. However, safety issues with regards to post-procedure platelet counts, haemoglobin (Hb) concentration or other haematological decrements in donors undergoing plateletpheresis have been only minimally explored. A literature search on this subject provided controversial data, in that increases in Hb concentration, haematocrit (Hct), and white blood cell (WBC) count was found after plateletpheresis in one study, whereas other authors described significant falls in these parameters. As far as concerns India, early studies on plateletpheresis recorded pre-donation low normal platelet and Hb values among most healthy donors. With the notion that plateletpheresis in these donors could cause significant decrements in haematological values (**sudipta sekhar das et.al**)

2. PLATELET

Since platelet was first identified in 1881, there has been continuous and accelerating progress in our basic understanding of platelet function and its utilization in various bleeding disorders. The first successful attempt to raise the platelet count in thrombocytopenic patients by transfusion of whole blood was described by Duke in 1910. General improvement of the technique to separate platelets from whole blood and the availability of plastic bags in blood banking revolutionized the field of component therapy. Platelet transfusions are the primary therapy for thrombocytopenia due to various causes. Thrombocytopenia may be due to qualitative defect, i.e. a defect in platelet function or quantitative defect i.e. decreased platelet count which can be seen in various haematological patients either due to primary disease or chemotherapy. Two types of platelet concentrates are available for transfusion; one which is the co-product of normal blood donation i.e. random donor platelets (RDP), (platelet rich plasma-platelet concentrate (PRP-PC) and Buffy coat poor-platelet concentrate (BC-PC) and the other is single donor platelets (SDPs), (apheresis-PC,) collected from voluntary thrombocytapheresis donors with the help of an automated cell separator. The basic principle behind the preparation of components from whole blood is that each component has its specific gravity and by applying centrifugation, each component is separated and removed, thus allowing the transfusion of the desired component according to the need of the patient. The recommended shelf life of platelet concentrates in presently available platelet storage bags is 5 days at 22±2°C with continuous agitation. The platelets undergo various storage changes starting from the collection, processing to storage and the underlying conditions within the patients, which may affect the therapeutic benefit to the recipient. (**Asian J Transfuse Sci. 2009 July**)

3. APHERESIS

The word apheresis is derived from a Greek word that means to separate or to take away. Initially, it referred to a manual process in which whole blood was withdrawn from the donor, centrifuged, plasma retained, and red cells returned to the donor. The development in the 1970s and 1980s of automated cell separator devices has changed the approach to apheresis and has resulted in the routine application of this methodology to the collection of blood components for transfusion, as well as the treatment of certain diseases. Apheresis is the primary source of plasma for fractionation because multiple units of plasma may be obtained without causing iron deficiency in the donor. Apheresis technology is commonly used to collect platelets because a full therapeutic dose of platelets (equivalent to six whole blood-derived platelet units) or even as many as three therapeutic doses (equivalent to 18 whole blood-derived units) can be obtained from one apheresis donation. Apheresis technology is also used for therapeutic plasma exchange and for the collection of peripheral blood hematopoietic progenitor cells. Membrane filtration can be combined with apheresis to collect plasma (**Wintrobe's clinical haematology 10th edn**)

At one of the components of blood can be removed and the procedure is specified for the component selected. The process of removing the plasma from the red cell is termed plasmapheresis. Similarly, the term is given for the removal of another component, including platelet (plateletpheresis), Red cells (erythrocytapheresis) or leukocytes (leukapheresis). Apheresis can be non-therapeutic or therapeutic. It can be done manually or using automated equipment. The most common reason behind the growing demand for plateletpheresis is the increasing awareness of specific component therapy and the increasing awareness about the risk associated with blood transfusion among clinical specialists. (**P. Pandey et.al/transfusion and apheresis science 2012**)

4. METHOD

4.1 Continuous flow centrifugation (CFC)

Continuous flow centrifugation (CFC) historically required two vein punctures as the "continuous" means the blood is collected, spun, and returned simultaneously. Newer systems can use a single vein puncture. The main advantage of this system is the low extracorporeal volume (calculated by volume of the apheresis chamber, the donor's Hematocrit, and total blood volume of the donor) used in the procedure, which may be advantageous in the elderly and for children.

4.2 Intermittent flow centrifugation

Intermittent flow centrifugation works in cycles, taking blood, spinning/processing it and then giving back the necessary parts to the donor in a bolus. The main advantage is a single vein puncture site. To stop the blood from coagulating, anticoagulant is automatically mixed with the blood as it is pumped from the body into the apheresis machine. (**R.N.Makroo, a compendium of transfusion medicine**)

4.3 Types of apheresis

There are numerous types of apheresis:

Blood taken from a healthy donor can be separated into its component parts during blood donation, where the needed component is collected and the “unused” components are returned to the donor. Fluid replacement is usually not needed in this type of collections.

There are large categories of component collections:

- a) **Plasmapheresis- blood plasma.** Plasmapheresis is useful in collecting FFP (fresh frozen plasma) of a particular ABO group. Commercial uses aside from FFP for this procedure include immune globulin products, plasma derivatives, and collection of rare WBC and RBC antibodies.
- b) **Erythrocytapheresis-red blood cells.** Erythrocytapheresis is the separation of erythrocytes from whole blood. It is most commonly accomplished using the method of centrifugal sedimentation. This process is used for red blood cell diseases such as sickle cell crises or severe malaria. The automated red blood cell collection procedure for donating erythrocytes is referred to as 'Double Reds' or 'Double Red Cell Apheresis.
- c) **Plateletpheresis (thrombocytapheresis)-blood platelets.** Plateletpheresis, like it sounds, is the collection of platelets by apheresis; while returning the RBC's, WBC's, and component plasma. The yield is normally the equivalent of between six and ten random platelet concentrates. Quality control demands the platelets from apheresis be equal to or greater than 3.0×10^{11} in number and have a pH of equal to or greater than 6.2 in 90% of the products tested and must be used within five days.
- d) **Leukapheresis leukocytes (white blood cells).** Leukapheresis is the removal of PMN's, basophiles, eosinophil's for transfusion into patients whose PMN's are ineffective or traditional therapy has failed. There is limited data to suggest the benefit of granulocyte infusion. The complications of this procedure are the difficulty in the collection and short shelf life (24 hours at 20 to 24°C).
- e) **Plasma exchange-**removal of the liquid portion of blood to remove harmful substances. The plasma is replaced with a replacement solution.
- f) **LDL apheresis-**removal of low-density lipoprotein in patients with familial hypercholesterolemia.
- g) **Photopheresis-**used to treat graft-versus-host disease, cutaneous T-cell lymphoma, and rejection in heart transplantation. Immunoabsorption with Staphylococcal protein A -agarose- column removal of allo-and auto antibodies (in autoimmune diseases, transplant rejection, hemophilia) by directing plasma through protein A-agarose columns. Protein A is a cell wall component produced by several strains of Staphylococcus aureus which binds to the Fc region of IgG. (**Wikipedia the free encyclopedia**)

5. PROCEDURE

Platelet separation can be done by two methods:

- a) **Single needle method (PLT-5d-SN Program)**-single needle” procedures a set volume is drawn and processed in the first part of the cycle and returned in the second part. The donor's blood undertakes 3-4 cycles of the draw and return
- b) **Double-needle method (PLT-5d Program)**-Double needle” procedures using both arms tend to be shorter since the blood is drawn and returned through different catheters

6. MATERIALS AND METHODS

The present prospective study was carried out in the department of transfusion medicine Forties Escorts Heart Institute, New Delhi from Sept. 2011 to Feb. 2012. The present study carried out to evaluate the platelet collection from apheresis devices and compare the efficiency of platelet collection processing time platelet yield and ACD used of Fresenius kabi com.tec total of 240 donors was subjected for apheresis out of them 71 were SN apheresis and 169 were DN apheresis procedure in which 229 male donors and 11 are female donors.

Donor-cell separator selection was subject to the availability of particular separator at the time of the procedure. All procedure was performed by the same resident doctors using fresenius.com Tec separator.

All plateletpheresis procedure was performed following the departmental standard operating procedure using closed system apheresis kit and ACD-A anticoagulant in the proportion of 1:12¹¹. The end point of each procedure was based on the target yield of 3×10^{11} platelets per unit platelets per unit maintaining a blood flow rate for all collections at 50-80 mL/min. To measure the pre- and post-donation haematological values, whole blood samples were collected in EDTA vials just before and within 30 minutes after the procedure. Parameters such as Hb concentration, Het, platelet and WBC counts, mean platelet volume (MPV) and platelet distribution width (PDW) were measured on a calibrated automated analyzer.

7. GUIDELINE FOR THE COLLECTION OF PLATELETS PHERESIS

7.1 Eligibility for donation

If you meet the requirements for donating blood, you probably can give platelets, Apheresis donors must;

- Be at least 18 years old
- Be in good health
- Weigh at least 110 pounds
- Not have taken aspirin or products containing aspirin 48 hours prior to donation.

7.2 Donor selection

Accept only voluntary non-remunerated blood donors if the following criteria are fulfilled. The interval between blood donations should be no less than three months for male donors and no less than six months for female donors.

The donor should be in good health, mentally alert and physically fit and should not be a jail inmate or a person having multiple sex partners or a drug addict.

7.3 Conditions for permanent deferral

- Cancer (malignancy)
- Heart diseases
- Abnormal bleeding tendencies
- Unexplained weight loss
- Diabetes controlled on insulin
- Hepatitis B and C Infection
- Chronic nephritis
- Signs & symptoms suggestive of AIDS
- Severe Liver disease (cirrhosis, carcinoma liver, acute hepatitis)
- Epilepsy
- Acute Asthma
- Active Leprosy
- Severe Endocrine Disorders
- Schizophrenia
- Active Tuberculosis
- Polycythaemia Vera
- HIV infection/AIDS
- Risk behaviour (homosexuals, heterosexual relations with commercial sex worker (CSW), IV drug abusers)

7.4 Conditions for temporary deferral

Conditions	Period of deferment
1. Abortion	6 months
2. H/O Blood transfusion	12 months
3. Alcohol intake	Till intoxicated
4. Minor Surgery	3 Months after recovery
5. Major Surgery	6 Months after recovery
6. Typhoid	12 Months after recovery
7. H/O Malaria, duly treated	3 Months (endemic)
8. Tattoo	6 Months
9. Acute Nephritis	6 Months after recovery
10. Breast Feeding	12 Months after delivery
11. Vaccination	
a. Killed/toxoid	No deferral if symptom free (DPT, TT, Typhoid, Paratyphoid, Cholera, Influenza Salk Polio vaccine, plague, Rabies as prophylactic and not after dog bite)
b. Prophylactic Hepatitis B	Defer for 5 days
c. HB IG	12 Months
d. Live attenuated (Measles, Mumps, Oral Polio, Yellow fever, Smallpox)	2 Weeks from the time of vac.
e. Anti-venom serum, anti-tetanus Serum, Anti-diphtheria serum, rubella	4 Weeks from time of vac.
12. Asthmatic on steroid	Defer (up till taking steroids)
13. Chronic sinusitis	No deferral unless using antibiotics
14. Rabies Vaccination after bite of rabid animal	1 year after bite
15. H/O Hepatitis in family or close contact	12 months
16. Immunoglobulin	12 months
17. Jaundice	
Hepatitis B	Deferred permanently
Hepatitis C	Deferred permanently
If type not known	Defer for 1 year
18. Hypertension	Mild hypertension and under control (diet/mild medication-diuretics, beta blockers, amlodipine Should be taking only one medicine out of the above (which may contain one or two salts). Defer if taking two medicines (which may contain one salt each). (Medical Officer decides on the fitness)
19. Antibiotics (Oral)	72 hours and till symptom free injection- 4 days and till symptom free/after the last injection.
20. Aspirin	After 72 hours. If aspirin is taken in the defined period, Platelets should not be made (collection can be done, put a big star on the platelet Bag and a not 'no platelets' on form
21. Cold/cough	Accepted if no fever and expectoration (if present) is not purulent.
22. Open wound (skin breached)	Accept when healed
23. Dental Extraction	3 days L/A, 1 month G/A
24. Dengue	Without blood transfusion-3 months with blood transfusion-1 year

25. Tuberculosis	5 years after cessation of symptoms and completion of treatment
26. Diabetic on oral medication	No deferral (if no Diabetic complication, especially vascular complication, present, as far as can be ruled by Medical History)
27. Sex outside Marriage	1 year non-CSW

7.5 The following can be accepted:

- Tetracycline and other antibiotics are taken to treat acne.
- Topical steroid preparations for skin lesions (but not at the venipuncture site).
- Oral contraceptives, replacement hormones, weight reduction pills, lipid-lowering drugs.

7.6 Physical examination, General appearance:

- Donor should be in good health, mentally alert and physically fit. If the donor is excessively nervous at the time of donation make her calm by talking to him/her and providing reassurance.
- **Age:** Any healthy adult donor between 18 and 60 years of age can donate blood.
- **Weight:**
45 kg: Can safely donate 350 ml of blood.
55 g and above: Can safely donate 450 ml of blood.
- **The frequency of donation:**
Male: after every 3 months.
Female: after every 6 months.
- **Temperature:** Not exceed 37.5 ± 0.2 °C / 98.6 ± 0.5 °F
- **Pulse:** 50 to 120/min and regular. Whenever a pulse is more than 100 beats per minute, check for its character. It should be regular.
- **Blood pressure:**
Blood pressure should be not higher than 170 mm of Hg systolic and 100mm of Hg. Diastolic. Lower limit- systolic pressure should not be below 100 of Hg, and diastolic should not be below 50mm of Hg.
- **Hemoglobin:** Haemoglobin should be more than /equal to 12.5 gm%.
- **Food:**
If Donor has not eaten anything for the past 3-4 hours, he/she should be given something to eat before donating blood.
- **Skin:** The skin at the vein puncture site, should be free from any lesion or scar of needle puncture, and, should not have any contagious skin diseases like – scabies, eczema etc.
- **Sporting activities:** If a donor has to go for any sporting activity immediately after donation, he should be advised against donation blood.
- For the Apheresis procedure, the criteria for donor selection remains the same as for whole blood donations but following things have to be taken note of:
 - A repeat donation is possible after 48 hrs. Up to a maximum of twice in a month and/24 times a year.
 - The phlebotomist must examine the donor for the presence of prominently visible veins in both the arms. Males are preferred.
 - The donor should not have taken aspirin/related drugs in the last 72 hrs.
 - Group of the donor should be confirmed by slide method to ensure that it is compatible with the patient's group.

Following group confirmation, the donor is required to fill up the registration form and is physically examined by medical personnel. EDTA sample is obtained from the patient for TML testing, reverse grouping and pre-donation platelet count. The donor should be informed that the testing would take around 45 minutes and meanwhile they can have something to eat. The donor should also be clearly explained the long duration of the procedure (2-3 hrs.)

The results of the test should be noted on the donor form.

If the TML results are negative the remaining charges for the procedure (Rs 8500) should be obtained from the patients' attendant and the donor Id label should be struck on the donor form. If the results for any of the infectious diseases test are positive they should be communicated to the doctor in charge who in turn would explain it to the donor.

8. METHODS

Platelet separation can be done by two methods:

- a) **Single needle method (PLT-5d-SN Program)**
- b) **Double-needle method (PLT-5d program)**

9. MATERIALS REQUIRED FOR PLATELETPHERESIS

9.1 Equipment

- Donor Couch
- Apheresis machine
- Apheresis kit
- ACD Solution
- Normal Saline
- Dielectric Sealer
- Rapid TML tests kits

- Tubes, slides, anti-sera and reagent cells
- Calcium tablets
- Betadine
- Spirit
- Micropore
- Steel tray
- Needle destroyer
- Bandage

9.2 Materials required for other procedures

EDTA and Plain Vaccutainers, Test Tube Stand.

CELL COUNTER (BACKMAN OR SYSMAX COULTER)

10. PRINCIPLE FOR PLATELET PHERESIS

After priming is complete, the donor's whole blood is mixed with ACD solution and pumped into the separation chamber in the centrifuge. Plasma is also pumped into the whole blood entering the separation chamber to maintain the blood in the chamber if the ideal haematocrit for efficient separation. In the separation chamber, anti-coagulated whole blood is separated into PRP (platelet rich plasma) and packed red blood cells. The PRP is pumped from the separation chamber into the collection chamber.

The primary stage of separation takes place in the separation chamber. As the blood enters the separation chamber, the higher density blood components, primarily RBCs are packed by centrifugal force towards the outer edges of the chamber.

These heavier blood components then exit the separation chamber via the PRBC line. The lower density component such as plasma and platelet can then be removed by the PRP pump via the PRP line. The PRP is pumped into the collection chamber where the secondary stage of the component separation takes place.

As the PRP enters the collection chamber, the heavier components (platelets are packed by centrifugal force against the outer wall of the chamber. The separated components remain in the chamber while the lower density plasma exit through the plasma line.

10.1 Procedure of Plateletpheresis

A. The platelet apheresis procedure comprises the following steps:

- a) Donor selection
- b) Installation of the apheresis kit
- c) Priming
- d) Separation
- e) Reinfusion
- f) Removal of the apheresis kit
- g) Labelling and issue

B. Installation of kit

- a) Single needle procedure for the collection of platelets.
- b) Turn power on by pressing the 'I' key on the right side of the machine.
- c) When the battery has completely discharged, the device can be turned on by simultaneously pressing the key and the override switch on the rear of the device.
- d) The screen would display the software version installed. Press continue key.
- e) Use arrow keys (↑ and ↓) to select the program group Platelet Donation. Press the OK key.
- f) Use the (↑ and ↓) keys to select the PLT-5d-SN program. Press the OK key,
- g) The message install set SSL is displayed (the PLT-Sd-SN program requires the SSL setting. With this program, platelets are separated in continuous mode using single needle method).
- h) Deposit the packing on the centrifuge door.

More Help key is used to browse through the available help screens to install the apheresis kit. These help screens are total 5 in number. Suspend the connecting lines laterally at the upper right of the device. Suspend the concentrate bag from the rear hook on the left of the device. Suspend the empty bag above clamp 4.

After installation is complete visually verify the following:

- The red clamp on the inlet line below the branch to the pre-sampling bag, the clamp on both the sampling bags, the white needle clamps, the clamp between concentrate bags, and the clamp on the plasma bag, must be closed.
- All other stop clamps must be open.
- The separation chamber must be correctly installed.
- The cell detector and the ACD drip chamber must be correctly installed.
- The return line is installed in clamp 1
- The saline line must be installed in clamp 2
- The plasma line must be installed in clamp 4
- The line leading to the empty bag must be installed in clam 5
- Press the continue key.

C. Priming

- a) Prior to priming connect the ACD bag to the green connector and hang it from the upper left hook on the front of the device.
- b) De-aerate the ACD drip chamber by pressing it and set the level to approximately 1cm, so that the fluid level is approximately 1cm below the optical sensor.
- c) Connect the saline bag to the transparent connector. Hang the saline bag from the front left hook.
- d) Press the Prime key on the screen. There will be an alarm test followed by priming.
- e) Once set is primed press Menu and using the arrow keys set the procedure values namely Blood flow (keep at around 45-50 ml/min at the beginning and increase later if feasible) ACD: Blood (this value should be kept at about 1:8 at the beginning of the procedure and later decreased), PLT Yield.
- f) Press Donor values on the screen and set the values. Again press OK to save these changes.
- g) Apply cuff to the fully extended and relaxed arm of the donor. To ensure the cuff contains no air, press the red deflation valve on the pressure pump and by pressing the cuff with your own hand. It is then imperative to close the red valve again to prevent malfunctions in the separation program. With all air removed the pressure gauge on the cuff should indicate 0.
- h) Press the continue key.

D. Separation

- a) Prepare separation would be displayed on the screen. Follow the displayed instructions and press-continue.
- b) Press the start key. This would inflate the cuff up to a pressure of approximately 50 mm of Hg. Now press the continue key. Follow the instructions displayed.
- c) The screen would display start separation. Press the start key.
- d) Place the ball in the donor's hand and instruct the donor to open and close his fist. This action has to be done and stopped alternative with each alarm corresponding to the separation and return phase of the cycle respectively.
- e) Press the options key. Go to Print parameters and press OK to print the parameter list.
- f) At a later stage, the blood flow of the donor can be increased if found suitable.
- g) Give the donor calcium tablets telling him/her to suck/chew these.

E. Reinfusion

- a) When the target yield has been achieved the separation will be automatically terminated.
- b) Follow the instructions displayed on the screen. If the saline bag is not empty the saline return can be continued for 20 ml each time the START key is pressed.
- c) Press continue to start rein fusion which would take another few minutes.
- d) At the end of reinfusion press the stop key.
- e) Close the blue clamp of the return line and press the continue key.
- f) Removal of the apheresis kit.
- g) Disconnect the donor and press the continue key.
- h) Seal off the concentrate bag and remove the set. Press the continue key.
- i) Check the printout and press OK.
- j) After the report has been printed, the device can be started for another separation by pressing the RESET key.
- k) Press the O key to switch off the device.

F. Labeling and Issue

- a) Collect the sample and obtain the post platelet count on the electronic counter. Record the result in the apheresis register along with the printout.
- b) On completion of reinfusion thoroughly mix the concentrate. Allow the concentrate bag to rest for 1hr and then agitate the bags on a suitable agitator for a minimum of 30 minutes. In case of emergency, the platelets can be issued immediately.
- c) Give the concentrate bag to the component lab for labeling.

10.2 Pre collection procedures

In the present prospective study firstly the donor is screened for the donation. Besides carrying the routine procedures as for a blood donor selection and screening procedure the following test was done:

- a) General history and vital parameters are checked.
- b) The blood group of the donor is confirmed, compatibility of the product in the order of preference is as given below:

Table 1: Compatibility of the product

Patient group	Compatibility groups in order of preference
O	O,AB,A,B
A	A, AB
B	B, AB
AB	AB

- c) Both the antecubital areas are checked for good venous access for the procedure.
- d) The last date of donation is noted, the donor is accepted after three days of platelet donation or one month of a whole blood donation.
- e) A sample of the donor is collected preferably have been the dorsum of the hand, one in the plain tube for infectious marker testing and one in EDTA for platelet count and blood grouping.
- f) The test is infectious marker was done by rapid procedure & the kits used for following tests were:

- HbsAg by manual ELISA or automated ELISA or by hepa card method.
- HIV & HCV by manually ELISA or automated ELISA or by tri-dot method.
- Malaria by strip and card method test.
- VDRL, TPHA, and strip are used for syphilis.
- Platelet count is done by cell counter- Beckman coulter or Sysmax.

10.3 POST COLLECTION PROCEDURES

After the procedure was over, a sample from the platelet product was collected in the sample pouch after one hour of completion of plateletpheresis to ensure correct platelet count.

Product platelet count was processed in cell counter- Beckman or Sysmax coulter

11. FRESENIUS COM. TEC OPERATING INSTRUCTIONS

The blood cell separator permits the collection of blood components from donors, therapeutic apheresis or therapeutic plasma exchange. The device is operated via a high-resolution color monitor with soft keys on either side. The monitor will only show those keys and user help messages required in the respective phase of the basically consists of the separation chamber, the pump lines, the drip chambers and the bags, is required for the separation procedure. Different sets are required depending on the procedure. The whole blood is separated in a separation chamber utilizing centrifugal force. The blood leak detector inside the centrifuge cabinet alerts the operator to prevent dangerous blood loss of the donor or the patient.

The whole blood and the individual blood components are transported by five peristaltic line pumps. The appropriate flow paths in the set are opened and closed by automatic clamps. The entire separation procedure is continuously monitored by various sensors ensuring the donor's or patient's safety at all times. In the event of a critical condition, a warning or the alarm condition is displayed on the monitor and an audible signal is sounded. The device will simultaneously close the return clamp to separate the donor circuit from the machine circuit. The separation is stopped. In the event of a power failure, emergency operation of the pumps for a minimum of 10 minutes is ensured by the integral battery. During this time the blood can be returned to the donor.



Fig. 1: Fresenius.com.tec

11.1 Sysmax

All blood samples were drawn in K3EDTA-anticoagulated blood and run on a Sysmax SE 9500 within 8 hours of phlebotomy. The criteria for inclusion in the study were a platelet count of $150 \times 10^3/\mu\text{l}$ ($150 \times 10^9/\text{L}$) or less with an instrument generated platelet flag and all samples with a platelet count of $75 \times 10^3/\mu\text{l}$ ($75 \times 10^9/\text{L}$) or less. Samples were run successively through each analyzer in the auto- sampling mode within 1 hour of the initial CBC count. The sequence of the analyzers was randomized for each batch of 5 samples. Four samples contained insufficient volume to obtain results in the auto-sampling mode by all 3 analyzers (no results were given for 3 samples on the Ad via 120 and for 1 on the coulter LH 750).

11.2 Principal

The impedance principle, patented by Coulter in 1953, was the first automated method for platelet counting 13. The limitations of the impedance method are well known and include the inability to distinguish platelets from other particles were hand carried to the flow cytometry laboratory where they were stained and analyzed within 90 minutes. Peripheral blood smears were reviewed on all

study samples for the presence of erythrocyte or leukocyte fragments, marked microcytosis, giant platelets, and the presence of platelet clumps or fibrin strands. (Sandhaus et al 2002)

11.3 Calculation

Platelet yield and collection efficiency were calculated by the following formula. For the calculation of platelet yield and collection efficiency, the following parameters are required.

- Donor pre-platelet count
- Donor post-platelet count
- Volume for the product
- Blood volume processed
- ACD volume used

$$\text{Platelet Yield} = \text{Total volume of product (ml)} \times \text{Product count (plts/}\mu\text{)} \times \text{Conversion factor (1000 } \mu\text{/ml)}$$

$$\text{Collection Efficiency} = \frac{\text{Platelet yield}}{\text{total platelet processed}} \times 100$$

Donor pre-procedure platelet-count and post-procedure platelet-count is used to calculate total platelet procedure

$$\text{Total platelet processed} = \frac{(\text{Pre count} + \text{Post count})}{2} \times \text{Total blood processed (ml)} \times 1000$$

(conversion factor) (Total blood volume processed = Blood volume processed (ml) – Anticoagulant used (ml).

12. STATISTICAL ANALYSIS OF DATA

The data were analyzed using SPSS statistical computer programme. The Spearman correlation was applied to a comparison between pre and post haematological values.

13. RESULTS AND OBSERVATIONS

The present prospective study was carried out in the department of transfusion medicine Forties Escorts Heart Institute, New Delhi from Sept. 2011 to Feb. 2012. The study was carried out with the aim to evaluate the effect of automated donation by fresenius.com.tec on the haematological values (HB, PLT count, WBC count, PDW, MPV) pre and post donation and to further evaluate the efficiency of platelet collection by fresenius.com.tec in terms of processing time, platelet yield, type of procedure(SN and DN) and ACD used.

A total of 240 donors were subjected for apheresis out of these 229 are male donor and 11 were a female donor and 71 donors were subjected to a donation by SN procedure and 169 underwent donation by DN procedure.

13.1 Age distribution of donor

Age of the donor accepted for donation at center of study is 18-60 years most of the donor between the age group of 21 to 30 years (52%) on both aphaeresis procedure SN and DN method and was closely followed by donor between 31 to 40 years (35%) of age very few donors were less than 20 years and more than 50 years of age (refer to table 3, bar chart in figure 2)

13.2 Distribution of number of PHPL by age group

Table 3: Distribution of number of PHPL by age group

Range in year	No. of Apheresis	Percentage
18-30	125	52%
31-40	84	35%
41-50	24	10%
51-60	07	03%

Majority of the donor (87%) was between the age group 18-40 years very few donors were (13%) observed between the age group of 41-60 years of age. (Refer to table 3, bar chart in figure 2)

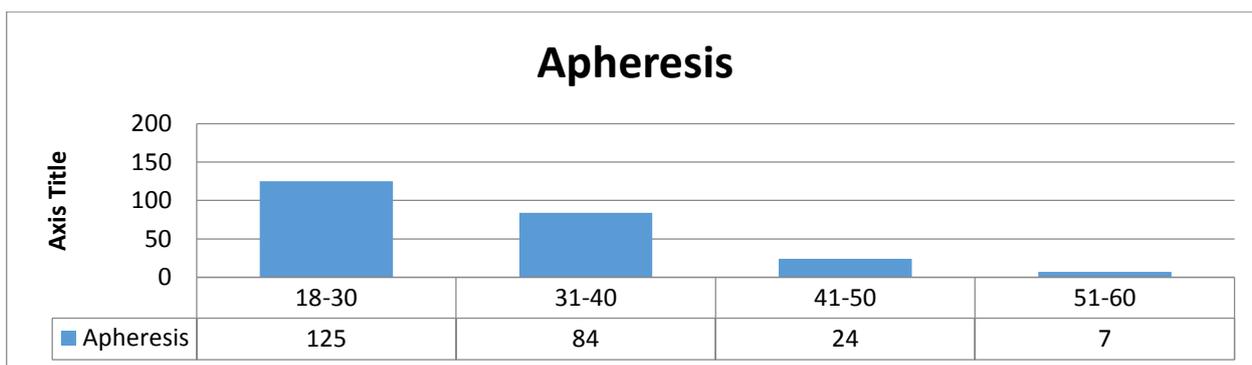


Fig. 2: Distribution of no of PHPL by AGE group

13.3 Sex distribution of donors

Total of 240 donors was subjected for apheresis out of them 229 male (95%) donor and 11 (5%) are a female donor. (Refer to the table 4, pie chart in figure 3)

Table 4: Distribution of no. of PHPL by sex

Total PHPL	Male	Percentage	Female	Percentage
240	229	95%	11	5%

Majority of the donor 95% is a male donor and very few 5% are a female donor.

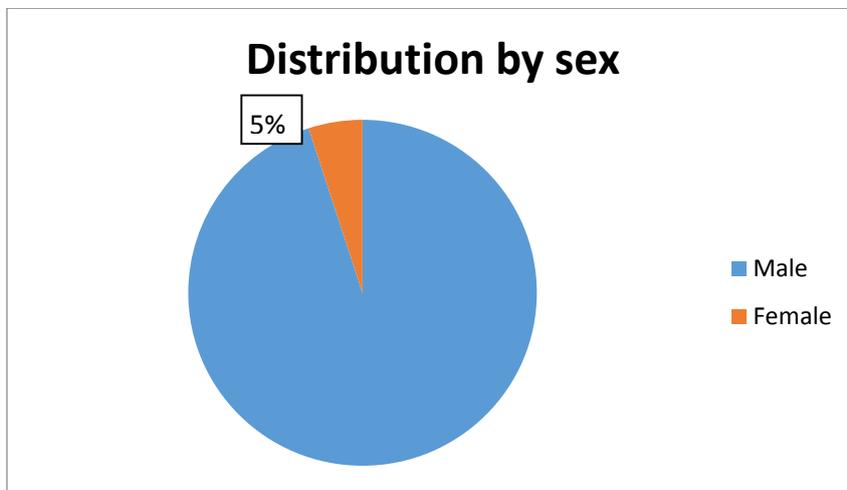


Fig. 3: Distribution of PHPL according to procedure type

Total of 240 donors was subjected for apheresis out of them 71 underwent SN apheresis and 169 were subjected DN apheresis procedure.

Table 5: Distribution of no of apheresis by the procedure

Donation	Single needle Procedure	Percentage	Double needle Procedure	Percentage
240	71	29.58%	169	70.42%

Majority of the donor (70.42%) underwent DN procedure refer to table 5, bar chart in figure 4.

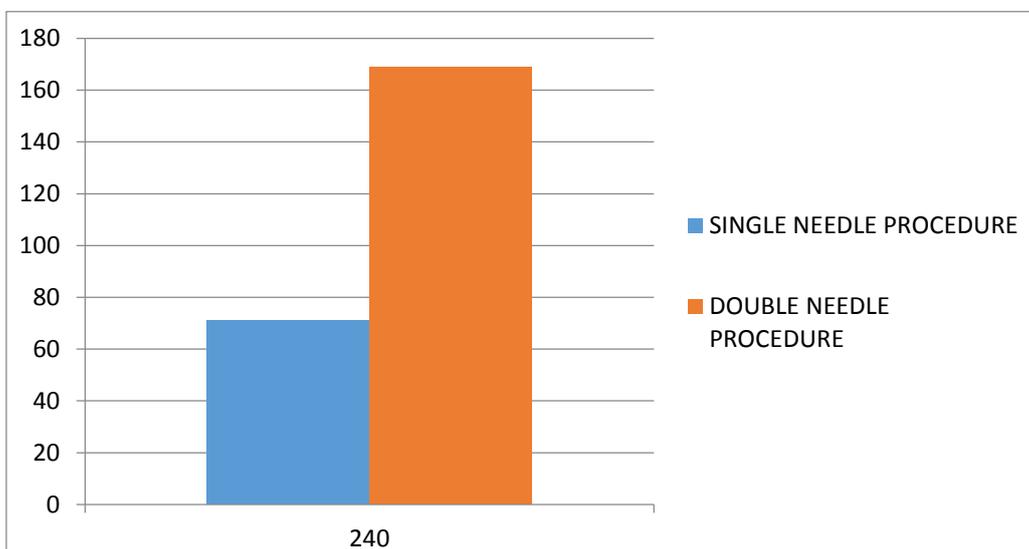


Fig. 4: Distribution of no. of apheresis by the procedure

13.4 Distribution of male and female donor in (SN and DN) procedure

Table 6: Distribution of male and female donor

Gender	DN	Percentage	SN	Percentage
Male	168	99.41%	61	85.92%
Female	1	0.59%	10	14.08%
Total	169	70.42%	71	29.58%

The majority of the donor was male in DN (99.41%) and in SN (85.92%) the female donor population was a (0.59%) in DN procedure and (14.08%) in SN procedure as inferred from above data the majority of the donor for PHPL were male. The percentage of the female donor was a little more in SN procedure (14.08%) as compared to DN procedure (refer to the table 6 and bar chart in figure 5)

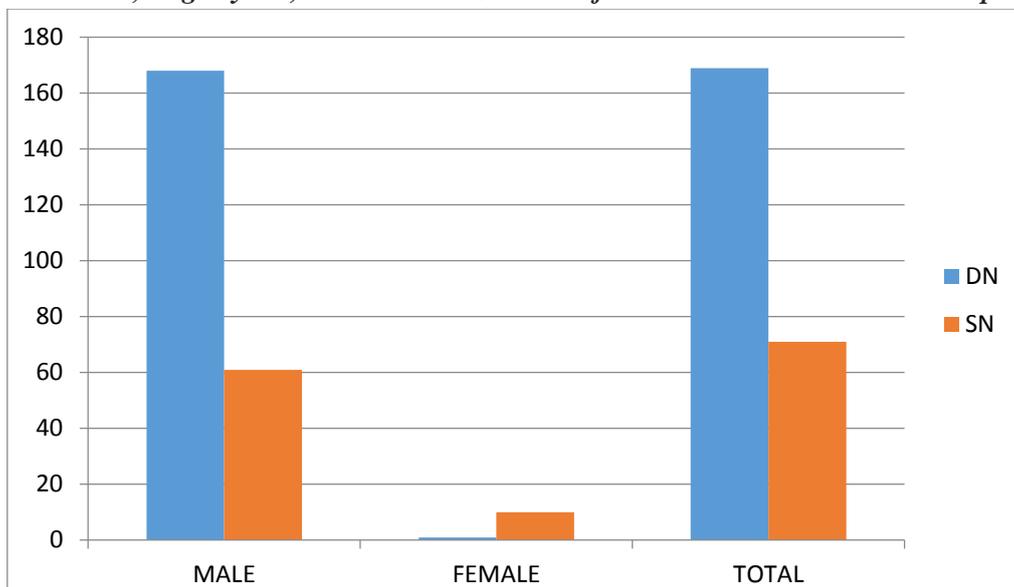


Fig. 5: Distribution of male and female donor

13.5 Comparison of mean haematological values of pre-donation and post-donation

Table 7: Comparison of mean haematological values of pre-Pltpheresis and post pltpheresis

Haematological values	Pre pltpheresis	Range	Post pltpheresis	Range
PLTCOUNT(lac/µl)	246	144-478	172	53-367
HB(g/dl)	15	12.5-20.9	14	10.2-19.5
WBC COUNT(cu/mm)	08	3.9-15.1	07	3.8-15
PDW (%)	13	8.5-18	13	8.4-18
MPV(fl)	09	6-13	09	7-13.1

The mean platelet count before apheresis was 246 lac/µl with the range of 144-478 lac/µl and the mean platelet count after apheresis 172 lac/µl with the range of 53-367 lac/µl. The mean value of platelet count dropped significantly in post-donation. Similarly the mean Hb level before apheresis was 15 g/dl with the range of 12.5-20.9 g/dl and after apheresis 14 g/dl with the range of 10.2-19.5 g/dl the mean value of Hb dropped marginally in post-donation and the mean WBC count before the apheresis is $8 \times 10^3 / \text{mm}^3$ with the range of $3.9-15.1 \times 10^3 / \text{mm}^3$ and after apheresis it is $7 \times 10^3 / \text{mm}^3$ with the range of $3.8-15 \times 10^3 / \text{mm}^3$. There was no change in PDW and MPV before and after the apheresis (refer to table 7, bar chart in figure 6)

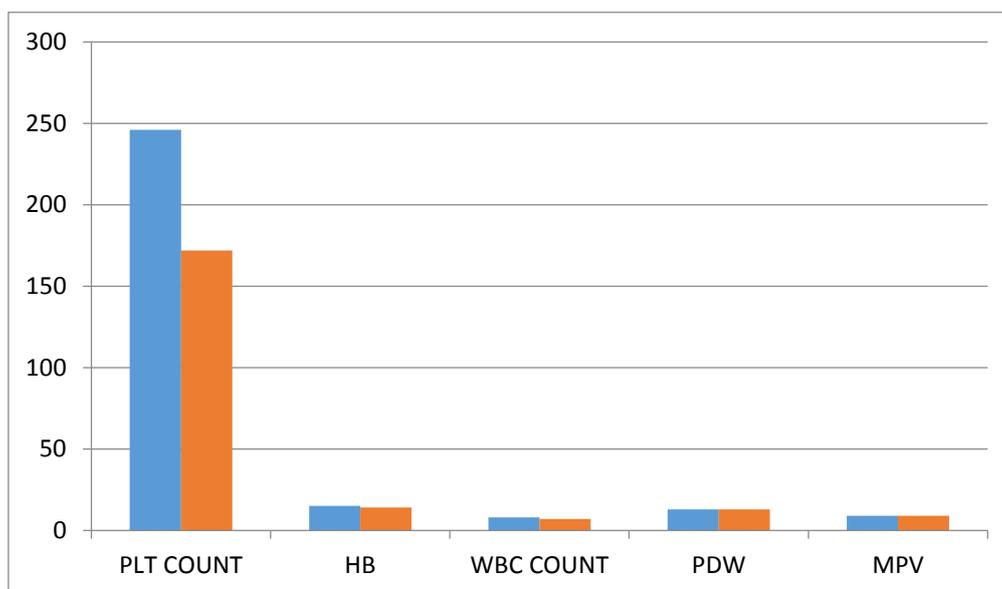


Fig. 6: Comparison of mean haematological values of pre-PHPL and post PHPL

13.6 Comparison of mean haematological values in pre and post-PHPL according to procedure type SN and DN

In SN procedure the mean platelet count pre-donation was 241.52 lac/µl with a range of 152-478 lac/µl the mean platelet count post donation was 169.59 lac/µl with a range 71-335 lac/µl the mean platelet count in DN procedure pre-donation was 247.88 lac/µl with range of 144-448 lac/µl and post-donation 173.50 lac/µl with range of 53-367 lac/µl the mean platelet count dropped significantly following apheresis procedure the mean platelet count between either of the procedure was not significantly different. In SN procedure the mean Hb pre-donation was 14.67 g/dl with range of 12.5-18.4 g/dl the mean Hb post donation was 14.7 with range of 10.2-18.2 g/dl the mean Hb in DN procedure pre-donation was 15.6 g/dl with range of 12.5-20.9 g/dl and in post donation was

14.6 g/dl with range of 12-19.5 g/dl the mean Hb dropped significantly following apheresis procedure the mean Hb level in either of procedure was not significantly different. After each procedure, there was no change in WBC count, PDW, and MPV. (Refer to table 8)

Table 8: Comparison of mean haematological values in SN and DN PHPL

Hm value	Sn				Dn			
	Pre	Range	Post	Range	Pre	Range	Post	Range
PLT COUNT/µl	241.52	150-478	169.59	71-335	247.88	144-448	173.5	53-367
HB(g/dl)	14.67	12.5-18.4	14.7	10.2-18.2	15.6	12.5-20.9	14.6	12-19.5
WBC COUNT	7.69	4.3-15.1	7.31	4.1-14.9	7.66	3.9-15.1	7.25	3.8-15
PDW	12.90	8.5-18	12.76	8.4-18	13.40	8.5-18	13.27	8.4-18
MPV	9.43	6-13	9.46	6.3-13.1	9.33	6-13	9.35	6.3-13.1

13.7 Comparisons of mean product yield, mean time taken, and mean final product count according to procedure type

Meantime taken in the procedure performed by SN was 86.48 min and in DN procedure it was 69.12 min. The product yield in SN was 3.10lac/µl and in DN it was 3.13 lac/µl and the difference of final product count is 8.85 lac/µl in SN and 8.95 lac/µl in DN according to mean values

Table 9: Comparison of mean product yield, the time is taken, and final product count

Parameter	Single needle	Double needle
Mean Product Yield (LAC/µL)	3.10	3.13
Meantime Taken (MIN)	86.48	69.12
Mean Fp Count (LAC/µL)	8.85	8.95

The product yield, final product count, and time are taken by DN procedure were comparatively better then with SN procedure. (Refer to table 9, bar chart in figure 7)

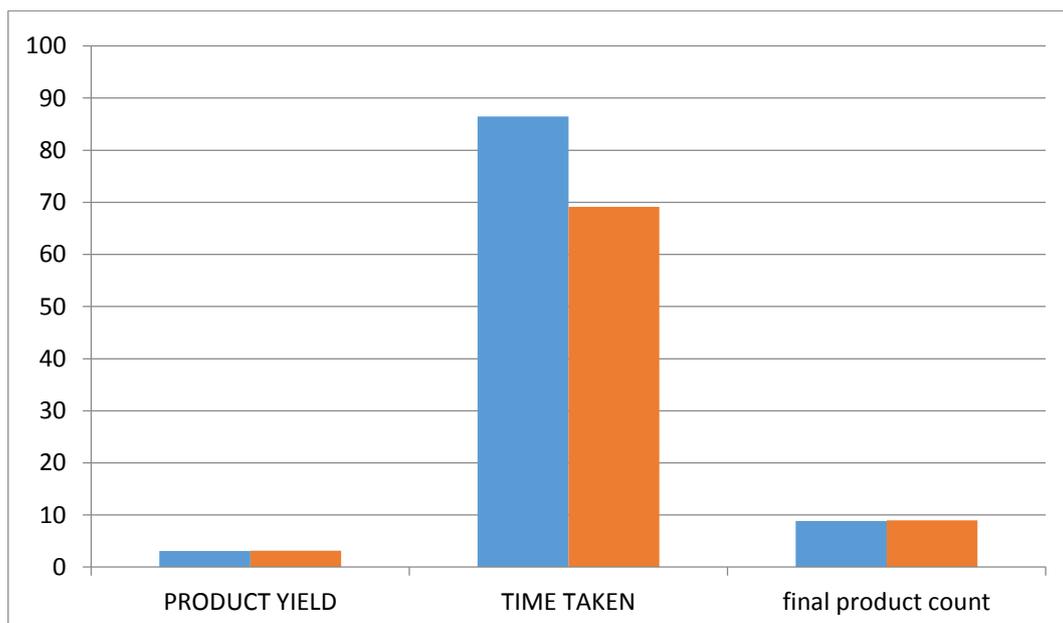


Fig. 7: Comparison of mean product yield, the time is taken, and final product count

Mean ACD volume used: The volume of ACD used varied from one procedure to another in the procedure performed on fresenius.com.tec it ranged from 220 ml to 460 ml with the mean of 306 ml.

13.8 Comparison of ACD volume in SN and DN

Table 10: Comparison of ACD volume in SN and DN

ACD(ML)	Minimum/ML	Maximum/ML	Mean/ML
SN	210	460	324.87
DN	210	410	297.75

The volume of mean ACD used by SN procedure was 324.87 ml with a range of (210-460 ml) mean ACD volume used was lesser in DN procedure when compared to SN procedure. (Refer to table 10, bar chart in figure 8)

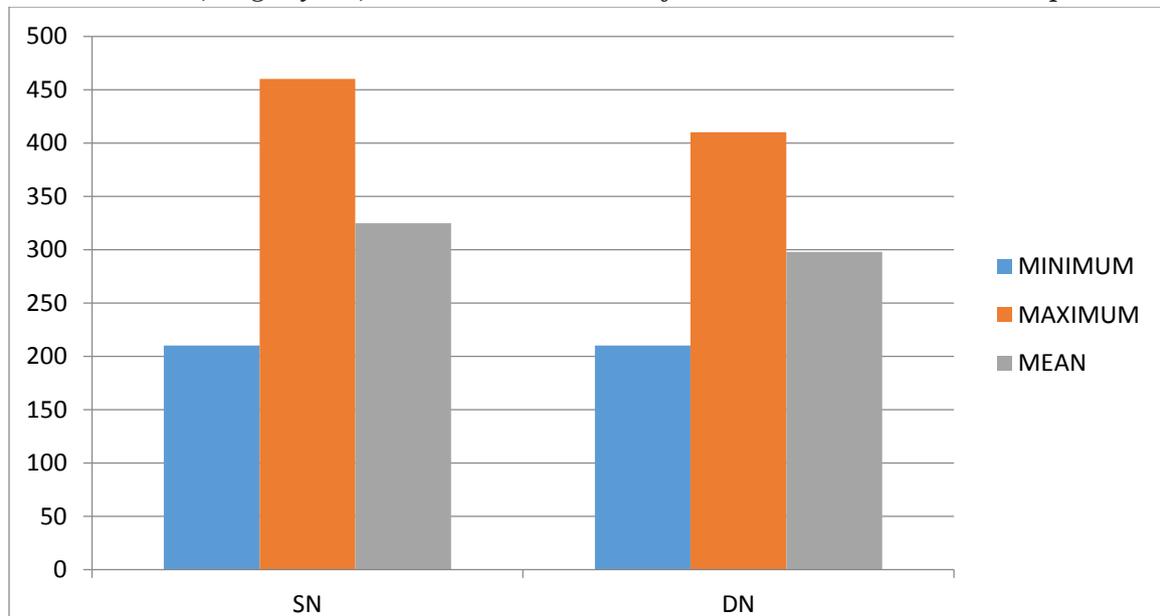


Fig. 8: Comparison of ACD volume in SN and DN

13.9 Overall distribution of mean pre and post donation haematological and efficiency parameter

Table 11: The overall distribution of mean pre and post donation haematological and efficiency parameter

Parameter	PreP C/ql	Post PC/ql	Product yield/ql	Pre Hb g/dl	Post Hb g/dl	Pre WBC /mm ³	Post WBC/ mm ³	Procedure duration on in min	Pre PDW (%)	Post PDW (%)	Pre MPV (fl)	Post MPV (fl)	ACD Vol (ml)
Mean value	246	172	3	15	14	8	7	74	13	13	9	9	306

The mean platelet count before apheresis was 246lac/ql and the mean platelet count after apheresis 172 lac/ql. The mean value of platelet count dropped significantly in post-donation. Similarly, the mean Hb level before apheresis was 15 g/dl and after apheresis 14 g/dl the mean value of Hb dropped marginally in post-donation and the mean WBC count before the apheresis is 8 X 10³/mm³ and after apheresis, it is 7 X 10³/mm³. There was no change in PDW and MPV before and after the apheresis (Refer to table 11, bar chart in figure 9)

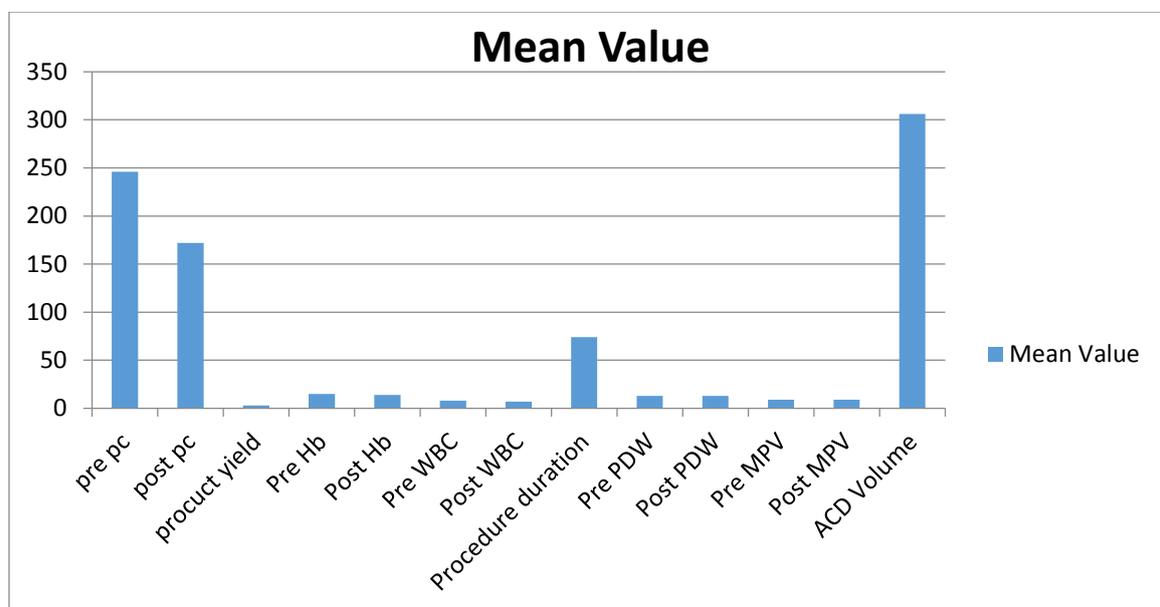


Fig. 9: The overall distribution of mean pre and post donation haematological and efficiency parameter

13.10 Overall comparison of pre platelet count with platelet yield

Correlations

Descriptive Statistics

Table 12: Correlations

	Mean	Std. Deviation	N
PrePLCo	245.9958	62.74745	240
Product Yield	3.1221	.40937	240

Table 13: Overall comparison of pre platelet count with platelet yield

		PrePLCo	Product Yield
PrePLCo	Correlation Pearson	1	.122
	Sig. (2-tailed)	.	.060
	N	240	240
Product Yield	Pearson Correlation	.122	1
	Sig. (2-tailed)	.060	.
	N	240	240

The comparison of overall pre-donation mean platelet count with mean platelet yield was carried out and student t-test was applied to ascertain the significance of value the p-value of 0.060 was not significant (Refer to table 11, 12 and 13, bar chart in figure 9 and 10)

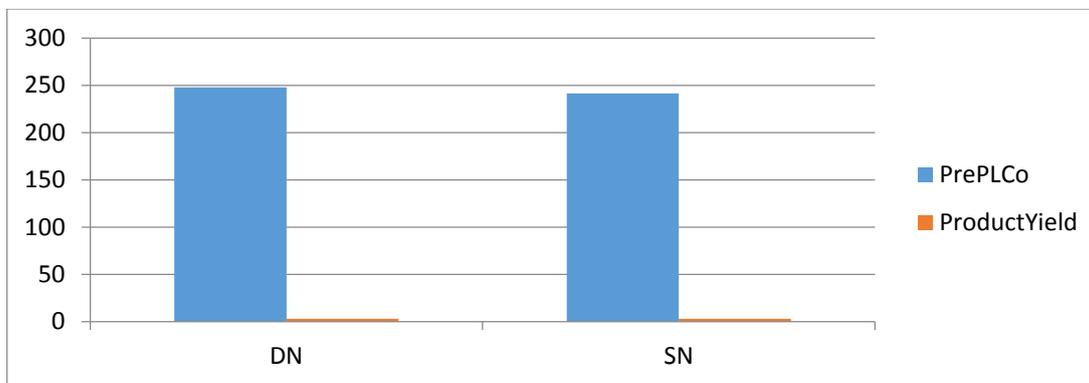


Fig. 10: Overall comparison of pre platelet count with platelet yield

T-Test

Table 14: Group Statistics

Procedure		N	Mean	Std. Deviation	Std. Error Mean
Pre PLT Co	SN	71	241.5211	64.45239	7.64909
	DN	169	247.8757	62.11522	4.77809
Post PLT Co	SN	71	169.5915	57.56477	6.83168
	DN	169	173.5030	56.64784	4.35753
Product Yield	SN	71	3.0990	.47018	.05580
	DN	169	3.1318	.38207	.02939
Final Product Count	SN	71	8.8548	1.34372	.15947
	DN	169	8.9476	1.09202	.08400
Pre Hb	SN	71	14.6662	1.33298	.15820
	DN	169	15.0556	1.23060	.09466
Post Hb	SN	71	14.0718	1.42239	.16881
	DN	169	14.6036	1.21101	.09315
Time Taken	SN	71	86.4789	28.07076	3.33139
	DN	169	69.1243	19.60812	1.50832
ACD Volume Used	SN	71	324.8732	58.96777	6.99819
	DN	169	297.7515	45.67507	3.51347

The overall mean value of various parameter of the present study were analyzed and to ascertain the Significant of the value the student t-test was applied and out of all the parameter the time taken in the procedure was found to be significant p-value was <0.000 and ACD volume used was also found to be significant were p-value is < 0.001 (Refer to table 14 and 15, bar chart in figure 11)

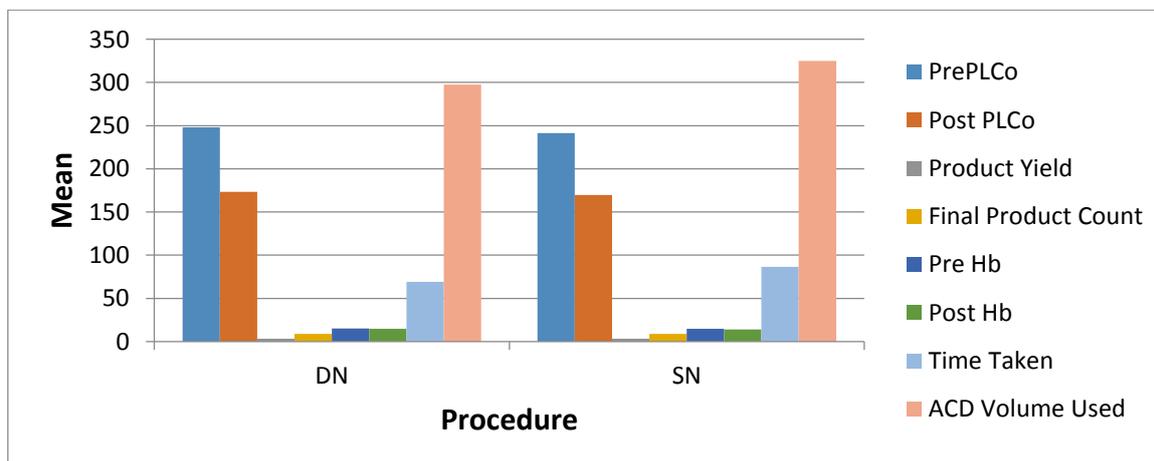


Fig. 11: Procedure

Table 15: Independent Samples Test

		Levene's Test for Equality of Variances				t-test for Equality of Means				
		F	Sig.	T	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Pre PLT Count	Equal variances assumed	.003	.953	-.715	238	.475	-6.35461	8.88328	-23.85451	11.14528
	Equal variances not assumed			-.705	127.216	.482	-6.35461	9.01880	-24.20090	11.49168
Post PLT Count	Equal variances assumed	.032	.858	-.486	238	.627	-3.91141	8.04991	-19.76957	11.94676
	Equal variances not assumed			-.483	129.606	.630	-3.91141	8.10308	-19.94284	12.12002
Product Yield	Equal variances assumed	1.256	.263	-.565	238	.573	-.03276	.05798	-.14698	.08146
	Equal variances not assumed			-.519	110.677	.604	-.03276	.06307	-.15774	.09221
Final Product Count	Equal variances assumed	1.264	.262	-.560	238	.576	-.09279	.16571	-.41922	.23365
	Equal variances not assumed			-.515	110.684	.608	-.09279	.18024	-.44996	.26439
Pre Hb	Equal variances assumed	2.404	.122	-2.183	238	.030	-.38942	.17842	-.74091	-.03794
	Equal variances not assumed			-2.112	122.557	.037	-.38942	.18436	-.75436	-.02449
Post Hb	Equal variances assumed	3.465	.064	-2.945	238	.004	-.53172	.18058	-.88745	-.17599
	Equal variances not assumed			-2.758	114.694	.007	-.53172	.19280	-.91364	-.14980
Time Taken	Equal variances assumed	15.494	.000	5.471	238	.000	17.35461	3.17236	11.10512	23.60411
	Equal variances not assumed			4.746	99.891	.000	17.35461	3.65693	10.09927	24.60996
ACD Volume Used	Equal variances assumed	10.807	.001	3.839	238	.000	27.12176	7.06475	13.20434	41.03918
	Equal variances not assumed			3.464	106.905	.001	27.12176	7.83065	11.59825	42.64527

13.11 The condition of donation donor deferral

During a total span of six months of study period donation was performed on 240 donors and 35 was temporarily deferred and 09 was permanently deferred for various reasons and the most common cause for donor defer for donation in present study was platelet count below 1.5lac/ql (10 deferred), Hb value below 12.5 g/dl (6 deferred). (Refer to table 16)

Table 16: Categories of donation donor deferral

Condition of deferral	Number of cases
Temporary	35
1. Platelet count below 1.5lac/ql	10
2. Low Hb below 12.5 g/dl	06
3. Poor venous access	02
4. Antibiotic and other medication	02
5. High blood pressure	03
6. Fever and other systemic problem	07
7. Weight less than 50 kg	03
8. Whole blood donation within last 3 month	01
9. Typhoid within 12 months	01
10. Permanent	09

14. DISCUSSION

Technical advances in automated cell separators have substantially improved the productivity and quality of the collection of apheresis platelets Goodnough et al 1998. Despotis G et al 1999. Various studies on automated plateletpheresis have been conducted to investigate the quality of platelet concentrates and its relation to biological contribution (platelet count and/or total mass) of the donor Burgstaler et al 1993 and Chaudhary R et al 2006. However, safety issues with regards to post-procedure platelet counts, hemoglobin (Hb) concentration or other haematological decrements in donors undergoing plateletpheresis have been only minimally explored.

A literature search on this subject provided controversial data, in that increases in Hb concentration, haematocrit (Hct), and white blood cell (WBC) count was found after plateletpheresis in one study, whereas other authors described significant falls in these parameters **love E et al 1993, beyan C et al 2003**. As far as concerns India, early studies on plateletpheresis recorded pre-donation low normal platelet and Hb values among most healthy donors. Das SS et al 2005, Chaudhary R et al 2006. With the notion that plateletpheresis in these donors could cause significant decrements in haematological values, there was a need for a study to observe the effect of automated plateletpheresis on the haematological values of donor population and the significance of such haematological alterations.

There are many advantages to donor plateletpheresis. Among these are the economic use of blood due to selective collection of a relatively large amount of components, possibility of more frequent donations, elimination of unnecessary component separation in the laboratory, reduced donor exposures and therefore reduced risk of disease transmission and risk of human leukocyte antigen (HLA) alloimmunization, use as an effective treatment for already alloimmunized patients, and labelling as 'leukoreduced' without further manipulation price **TH et al 2003, vassallo R et al 2003, vassallo R et al 2033, Ness p et al 2001, Slichter SJ et al 1998, Slichter GB et al 1996**.

Although improvements in apheresis technology are on-going, some problems do remain, e.g., the duration of the procedure and donor discomfort owing to the citrate used for anticoagulation.

The development in the field of medicine particularly in the area of oncology surgery and chemotherapy has led to increase in demands for the products to overcome the effects of the bone marrow suppression caused by the drug (**Denise M.harmening; 1999**). The transfusion safety of single donor platelet transfusion over whole blood-derived platelet concentrate has been well established. The potential advantage of SDP is that it reduces the number of donor exposures is to 4-6 fold, in terms of transfusion-transmitted infections and secondly a sufficient dose can be obtained from a single donor. Additionally, single donor platelet transfusion reduces the chance of a septic transfusion reaction as has been established in previous publications. In modern transfusion practice where the AABB and the American College of Pathologists have mandated the screening of platelets units for bacterial infection, apheresis platelets currently are the product of choice because they have a significant cost benefit over pooled platelet concentrate where each unit is tested for bacterial infections. (**Prashant Pandey et al; 2012**)

The present prospective study was carried out in the department of transfusion medicine forties escorts heart institute, New Delhi from Sep. 2011 to Feb. 2012. The study was carried out to evaluate the platelet collection from apheresis device and (Fresenius.com.tec) compare the efficiency of platelet collection, processing time, platelet yield and ACB used of Fresenius Kabi com.tec total of 240 donors was subjected for apheresis out of them 71 were SN apheresis and 169 were DN apheresis procedure.

Of which 229 were male donor and 11 was female donor.

At the center of study, a total of 240 donors were registered for plateletpheresis procedures during a total span of 06 months and procedures were performed on approximately 86% of the donors with the remaining 14% of donors deferred for various reasons.

The present study addressed donor safety issues with regards to reductions in haematological values after plateletpheresis. The greatest concern regards those donors with a low normal pre-donation platelet count ($144 - 478 \times 10^9 /L$) or Hb concentration (12.5 - 20.9 g/dl). In the present study, ten donors were found to have a pre-procedure platelet count of $<100 \times 10^9 /L$, fortunately with no clinical manifestations.

The mean value of pre and post apheresis plt count in present study was $246 \times 10^3 \text{ ql}$ and $172 \times 10^3 \text{ ql}$ respectively the value was lower than the value reported by love K et al 1993 they reported pre plateletpheresis platelet count 258 - 610^3 ql and post platelet apheresis 229 - 210^3 ql , however, the information can be used in establishing post donation reference range which could be utilized to assess the suitability of donor for subsequent donation. **Sudipta sekhar das et al 2009** reported pre platelet count 150 - $200 \times 10^3 \text{ ql}$ and after procedure platelet count $<100 \times 10^3 \text{ ql}$ **P Pandey et al in 2012** reported pre platelet count $237 \times 10^3 \text{ ql}$ **Stephen J. Wagner et al** have reported pre plateletpheresis count in SN was $139.6 \pm 139.6 \times 10^3 \text{ ql}$ and in DN it was $136.7 \pm 11 \times 10^3 \text{ ql}$.

The mean value pre and post apheresis Hb and WBC count in the present study was pre Hb 15 g/dl and post apheresis Hb 14g/dl and pre apheresis WBC count pre $08 \times 10^3 /\text{mm}^3$ and post WBC count $07 \times 10^3 /\text{mm}^3$ **P. Pandey et al in 2012** reported pre Hb 15.05 g/dl and pre WBC count 7200/ql **Beyan c et al in 2003** also reported that after PHPL; WBC, HB, and platelet count decreased significantly the finding is in close agreement with the present study, therefore, the haematological parameter should be monitored carefully in donor who is supposed to undergo long-term regular apheresis and to prevent the occurrence of an artificial anemia which is likely to happen and selection of cell separator system be based on this possibility.

The mean value of ACD used in present study in SN procedure 324.87 ml and in DN procedure it was 297.75 ml with the combined mean value in both procedure was 306 ml according to **Benjamin et al in 1999** reported 482 ml and **Tendulkar et al 2009** report $417.58 \pm 71.36 \text{ ml}$ consumption in apheresis procedure variation in ACD volume used might be due to the different make and models of apheresis devices used that is (CFC continuous flow centrifugation or (IFT) type intermittent flow centrifugation) and variation causes by variable donor distribution in procedure type (SN and DN).

The mean product yield in the present study was $3.10 \times 10^{11} /L$ in SN and in DN it was $3.13 \times 10^{11} /L$ and overall it was $3 \times 10^{11} /L$. **P. Pandey et al 2012** reported $3.1 \times 10^{11} /L$ **Moog et al 2003** reported $3.11 \pm 0.40 \times 10^{11} /L$ **Strasser et al 2005** reported $2.90 \pm 0.54 \times 10^{11} /L$ in com.tec **Burgstaler et al 1999** reported $5.03 \times 10^{11} /L$ in amicus **Benjamin et al** reported $3.3 \times 10^{11} /L$ in com.tec, the finding is in close agreement with the present study. According to SN and DN procedure the mean product yield in the present study was in SN is $3.10 \times 10^{11} /L$ and in DN it was $3.13 \times 10^{11} /L$ are in close agreement with **Stephen J. Wagner et al 2011** they reported the value in SN $4.1 \pm 0.3 \times 10^{11} /L$ and in DN $4 \pm 0.3 \times 10^{11} /L$.

In the present study the mean time taken in SN procedure was 86.48 min and in DN it was 69.12 min **P. Pandey et al 2012** reported the value in SN 70 min and in DN it was 50 min in present study the mean time taken in both procedure was 74 min **Burgstaler et al in 1999** reported 77 min and **Benjamin et al in 1999** reported 71.5 min the finding are close in agreement with present study. However, **Coffe et al 2001** reported 87 – 109 min and **Moog et al 2003** reported 55 ± 11 min **Strasser et al 2005** reported 54 ± 13 min.

The comparison of overall pre-donation means platelet count with mean platelet yield was carried out and student t-test was applied to ascertain the significance of value the p-value of 0.060 was not significant **Das ss et al 2005** reported. The mean platelet yield was $2.9 \pm 0.64 \times 10^{11}$. While a direct relationship was observed between pre-donation platelet count and yield ($r=0.51$, $P < 0.001$). The yield was $> \text{or} = 3 \times 10^{11}$ in $>80\%$ of procedures when the pre-donation platelet count was $> \text{or} = 250 \times 10^3/\text{mm}$. **Chaudhary R et al 2006** reported a relationship between pre-donation donor variables and yield of platelets was studied using the Pearson correlation. The mean platelet yield was $2.8 \pm 0.73 \times 10^{11}$. While a direct relationship was observed between pre-donation platelet count and yield ($r=0.50$, $p<0.001$). Optimization of platelet yield, which is influenced by pre-donation platelet count, is an emerging issue in blood transfusion services. Identification of such factors may help in selecting donors to obtain higher platelet yields and consequently better clinical outcome.

The overall mean value of various parameter of the present study were analyzed and to ascertain the significance of the value the student t-test was applied and out of all the parameter the time taken in the procedure was found to be significant p-value was <0.000 and ACD volume used was also found to be significant were p-value is <0.001 .

Total no. of deferral cases are 35 for temporary and 9 are permanent deferral donors the most common deferral donors are in the condition of below platelet count is 28.57% and below Hb level 17.14% and other are in fever and other systemic problem 20% rest of deferral donors are in other condition such as weight loss and other symptoms and in medication.

Significant reductions in donors' haematological values after plateletpheresis, albeit without clinical manifestations, have also been reported by other researchers. Lazarus et al 2001 did not find any donors with clinical thrombocytopenia among 939 regular donors who underwent 11,464 procedures. However, substantial drops in platelet counts could be a concern in our population in which approximately 36% of the healthy donors had a pre-donation platelet count of $<200 \times 10^9/\text{L}$ and were, therefore, predisposed to clinical thrombocytopenia

15. SUMMARY AND CONCLUSION

Technical advances in automated cell separators have substantially improved the productivity and quality of the collection of apheresis platelets **Goodnough et al 1998, Despotis G et al 1999**. Various studies on automated plateletpheresis have been conducted to investigate the quality of platelet concentrates and its relation to the biological contribution (platelet count and/or total mass) of the donor **Burgstaler et al 1993** and **Chaudhary R et al 2006**. However, safety issues with regards to post-procedure platelet counts, haemoglobin (Hb) concentration or other haematological decrements in donors undergoing plateletpheresis have been only minimally explored. A literature search on this subject provided controversial data, in that increases in Hb concentration, haematocrit (Hct), and white blood cell (WBC) count was found after plateletpheresis in one study, whereas other authors described significant falls in these parameters **love E et al 1993, Beyan C et al 2003**. As far as concerns India, early studies on plateletpheresis recorded pre donation low normal platelet and Hb values among most healthy donors. **Das SS et al 2005, Chaudhary R et al 2006**. With the notion that plateletpheresis in these donors could cause significant decrements in haematological values, there was a need for a study to observe the effect of automated plateletpheresis on the haematological values of donor population and the significance of such haematological alterations.

There are many advantages to donor plateletpheresis. Among these are the economic use of blood due to selective collection of a relatively large amount of components, possibility of more frequent donations, elimination of unnecessary component separation in the laboratory, reduced donor exposures and therefore reduced risk of disease transmission and risk of human leukocyte antigen (HLA) alloimmunization, use as an effective treatment for already alloimmunized patients, and labelling as 'leukoreduced' without further manipulation price **TH et al 2003, Vassallo R et al 2033, Ness p et al 2001, Slicher SJ et al 1998, Slicher GB et al 1996**. Although improvements in apheresis technology are on-going, some problems do remain, e.g., the duration of the procedure and donor discomfort owing to the citrate used for anticoagulation.

The development in the field of medicine particularly in the area of oncology surgery and chemotherapy has led to increase in demands for the products to overcome the effects of bone marrow suppression caused by the drug (**Denise M.harmening; 1999**). The transfusion safety of single donor platelet transfusion over whole blood derived platelet concentrates has been well established. The potential advantage of SDP is that it reduces the number of donor exposures is to 4-6 fold, in terms of transfusion transmitted infections and secondly a sufficient dose can be obtained from a single donor. Additionally, single donor platelet transfusion reduces the chance of a septic transfusion reaction as has been established in previous publications. In modern transfusion practice where the AABB and the American College of Pathologists have mandated the screening of platelets units for bacterial Infection, apheresis platelets currently are the product of choice because they have a significant cost benefit over pooled platelet concentrate where each unit is tested for bacterial infections. (**Prashant Pandey et al; 2012**)

Each country has its own rules to protect the safety of both donor and recipient. In a typical set of rules, a platelet donor must weigh at least 50 kg (110 lb) and have a platelet count of at least $150 \times 10^9/\text{L}$ ($150,000$ platelets per mm^3). One unit has about 3×10^{11} platelets. Blood accounts for about 8% of body weight, giving a 50 kg (110 lb) donor about four litres of blood. No more than 50% of platelets are ever extracted in one sitting, and they can be replenished by the body in about three days. Most newer apheresis machines can separate a dose of platelets in about 60 to 120 minutes depending on the donor's health condition.

The present prospective study was carried out in the department of transfusion medicine Forties Escorts Heart Institute, New Delhi from Sep. 2011 to Feb 2012. the study was carried out with the aim to evaluate the effect of automated donation by fresenius.com.tec on the haematological values (HB, PLT count, WBC count, PDW,MPV) pre and post donation and to further evaluate the efficiency of platelet collection by fresenius.com.tec in terms of processing time, platelet yield, type of procedure(SN and DN)and ACD used. A total of 240 donors were subjected for apheresis out of these 229 are male donor and 11 were a female donor and 71 donors were subjected to a donation by SN procedure and 169 underwent donation by DN procedure.

Majority of the donor (87%) was between the age group 18-40 years very few donors was (13%) observed between the age group of 41-60 years of age. Total of 240 donors was subjected for apheresis out of them 229 male (95%) donor and very few (5%) are a female donor. Total of 240 donors was subjected for apheresis out of them 71 underwent SN apheresis and 169 were subjected DN apheresis procedure. Majority of the donor (70.42%) underwent DN procedure.

The majority of donor was male in DN (99.41%) and in SN (85.92%) the female donor population was an (0.59%) in DN procedure and (14.08%) in SN procedure as inferred from above data the majority of donor for PHPL were male the percentage of female donor were a little more in SN procedure (14.08%) as compared to DN procedure.

The mean platelet count before apheresis was 246 lac/µl with the range of 144-478 lac/µl and the mean platelet count after apheresis 172 lac/µl with the range of 53-367 lac/µl. The mean value of platelet count dropped significantly in post donation. Similarly the mean Hb level before apheresis was 15 g/dl with the range of 12.5-20.9 g/dl and after apheresis 14 g/dl with the range of 10.2-19.5 g/dl the mean value of Hb dropped marginally in post donation and the mean WBC count before the apheresis is $8 \times 10^3/\text{mm}^3$ with the range of $3.9-15.1 \times 10^3/\text{mm}^3$ and after apheresis it is $7 \times 10^3/\text{mm}^3$ with the range of $3.8-15 \times 10^3/\text{mm}^3$. There was no change in PDW and MPV before and after the apheresis.

In SN procedure the mean platelet count pre donation was 241.52 lac/µl with a range of 152-478 lac/µl the mean platelet count post donation was 169.59 lac/µl with a range 71-335 lac/µl the mean platelet count in DN procedure pre donation was 247.88 lac/µl with range of 144-448 lac/µl and post donation 173.50 lac/µl with range of 53-367 lac/µl the mean platelet count dropped significantly following apheresis procedure the mean platelet count between either of the procedure was not significantly different. In SN procedure the mean Hb pre donation was 14.67 g/dl with range of 12.5-18.4 g/dl the mean Hb post donation was 14.7 with range of 10.2 - 18.2 g/dl the mean Hb in DN procedure pre donation was 15.6 g/dl with range of 12.5 - 20.9 g/dl and in post donation was 14.6 g/dl with range of 12 - 19.5 g/dl the mean Hb dropped significantly following apheresis procedure the mean Hb level in either of procedure was not significantly different. After each procedure, there was no change in WBC count, PDW, and MPV.

Mean time taken in the procedure performed by SN was 86.48 min and in DN procedure it was 69.12 min. The product yield in SN was 3.10lac/µl and in DN it was 3.13 lac/µl and the difference of final product count is 8.85 lac/µl in SN and 8.95 lac/µl in DN according to mean values.

The product yield, final product count, and time are taken by DN procedure were comparatively better then with SN procedure.

The volume of ACD used varied from one procedure to another in the procedure performed on fresenius.com.tec it ranged from 220ml to 460ml with the mean of 306 ml. The volume of mean ACD used by SN procedure was 324.87 ml with a range of 210 - 460 ml. The mean ACD volume used in DN procedure was 297.75 ml with a range of (210 - 410ml). The mean ACD volume used was lesser in DN procedure when compared to the SN procedure.

The comparison of overall pre donation means platelet count with mean platelet yield was carried out and student t test was applied to ascertain the significance of value the p value of 0.060 was not significant.

The overall mean value of various parameter of the present study were analysed and to ascertain the significant of the value the student t test was applied and out of all the parameter the time taken in the procedure was found to be significant p value was <0.000 and ACD volume used was also found to be significant were p value is <0.001.

During a total span of six months of study period donation was performed on 240 donors and 35 were temporarily deferred and 09 were permanently deferred for various reasons and the most common cause for donor defer for donation in present study was platelet count below 1.5 lac/µl (10 deferred), Hb value below 12.5g/dl.

On critical analysis of data following facts emerged:-

- On critical analysis of data that apheresis donor with low normal pre procedure platelet count $150 - 200 \times 10^9 /L$ and Hb concentrate 12.5-13 g/dl should be examined for post donation drops in these haematological parameters.
- A donor with significant decrements should be reviewed to screen them from a future donor so to avoid iatrogenic anaemia and thrombocytopenia.
- A comprehensive prospective study on this aspect is required to establish a guideline for donor safety in apheresis and also in assessing donor suitability. Especially with the double product apheresis collection.
- This information can be a value an establishing post donation range which could be utilised when reviewing the suitability of donors for subsequent donation.
- Haematological parameters should be monitored carefully in donor when are undergo long term regular apheresis.

16. REFERENCES

- [1] American Association of Blood Banking; Technical Manual:(1996).
- [2] Blood Book 2006.

- [3] Barrett V.J et al:(1995).
- [4] Diamond LK. A history of blood transfusion. In: Wintrobe MM, ed. Blood, pure and eloquent. New York: McGraw Hill, 1980.
- [5] Director General of Health Science technical manual 2nd edition.
- [6] Erslev AJ, Caro J, Schuster SJ. Is there an optimal haemoglobin level? *Trans Med Rev* 1989; 3:237.
- [7] Farr AD. The first human blood transfusion. *Med Hist* 1980; 24:143.
- [8] Goodnough LT, et al. A two-institution study of transfusion practice in 78 consecutive adult elective open-heart procedures. *Am J Clin Pathol* 1989;91:468.
- [9] Greenwalt TJ, Zelenski KR> Transfusion support for haemoglobinopathies. *Clin Haematol* 1984;13:151.
- [10] Harker LA, et al. Mechanish of abnormal bleeding in patients undergoing cardiopulmonary bypass: Acquired transient platelet dysfunction associated with the selective alpha-granule release. *Blood* 1980;2:56:824.
- [11] Hennery JB 1996.
- [12] Makroo RN,1999: Compendium of transfusion medicine, 2nd edition.
- [13] Murphy S, et al. Indications for platelet transfusion in children with acute leukemia. *Am J Hematol* 1982;12:347.
- [14] National Institutes of Health Consensus Conference. Perioperative red blood cell transfusion. *JAMA* 1988;260:2700-2703.
- [15] Petz LD. Blood Transfusion in acquired haemolytic anemias. In: transfusion medicine. 3rd ed. New York: Churchill Livingstone, 1996:469-499.
- [16] Slichtr SJ. Controversies in platelet transfusion therapy. *Ann Rev Med* 1980;31:509.
- [17] Shirey RS, Boyd JS, Ness PM (1994).
- [18] Wain SL. The controversy of unmodified versus citrated blood transfusion in the early 20th century. *Transfusion* 1984;24:404.
- [19] Wintrobe's Clinical Hematology 10th edition 1999.
- [20] Williams and Wilkins 1996.
- [21] World Health Organization: Geneva (A.I.T.B.S 2004).
- [22] Asian journal of transfusion science Volume 3 Issue 2 July-December 2009.
- [23] Practice Guidelines for Blood Transfusion A Compilation from Recent Peer-Reviewed Literature Second Edition.
- [24] Standards For Blood Banks & Blood Transfusion Services.
- [25] Official journal of the world apheresis association.
- [26] Official journal of the European Society for Haemapheresis.
- [27] Official journal of the societa italiana di emaferesie manipolazione cellulare.
- [28] Slichter SJ. Controversies in platelet transfusion therapy.
- [29] Slichter SJ, Harker LA. Thrombocytopenia: mechanisms and management of defects in platelet production. *Clin Haematol*.
- [30] Slichter SJ. Mechanisms and management of platelet refractoriness. In: Nance ST, ed.
- [31] A. Transfusion medicine in the 1990's. Arlington: American Association of Blood Banks.
- [32] Slichter SJ, Harker LA. Preparation and storage of platelet concentrate. I. Factors influencing the harvest of viable platelets from whole blood. *Br J Haematology*.
- [33] Slichter SJ, Harker LA. Preparation and storage of platelet concentrate. II. Storage variables influencing platelet viability and function. *Br J Haematology*.
- [34] Murphy S, Heaton WA, Rebullia P. Platelet production in the Old World- and the New. *Transfusion*.
- [35] Murphy S, Gardner FH. Effect of storage temperature on maintenance of platelet viability- the deleterious effect of refrigerated storage. *N Engl J Med*.
- [36] Murphy S. Platelet storage for transfusion. *Semin Hematology*.
- [37] Murphy S, Gardner FH. Platelet storage at 22^oC: the role of gas transport across plastic containers in the maintenance of viability.
- [38] Murphy S, Gardner FH. Platelet storage at 22^o; metabolic, morphologic, and functional studies. *J Clin Invest*.
- [39] Murphy S, Kahn RA, Holme S, et al. Improved storage of platelets for transfusion in a new container.
- [40] Hogge DE, Thompson BW, Schiffer CA. Platelet storage for 7 days in second-generation bags.
- [41] National AIDS Control Organisation.
- [42] Goodnough LT, Kuter D, McCollough J, Brecher ME. Apheresis platelets: emerging issues related to donor platelet count, apheresis platelet yield, and platelet transfusion dose. *J Clinical Apher*.
- [43] Goodnough LT, Ali S, Despotis G, et al. Economic impact of donor platelet count and platelet yield in apheresis products: relevance for emerging issues in platelet transfusion therapy. *Vox Sang*, 1999.
- [44] Burgstaler EA, Pineda AA, Brecher Ma. Plateletpheresis: comparison of platelet yields, processing time, and white cell content with two apheresis systems. *Transfusion*, 1993.
- [45] Hester JP, Ventura GJ. Modeling of platelet concentrate yield in continuous-flow cell separator devices. *J Clin Apher*, 1988.
- [46] Benjamin RJ, Rojas R, Christmas S, et al. Plateletpheresis efficiency: a comparison of the Spectra LRS and AMICUS separators. *Transfusion*, 1999.
- [47] Das SS, Chaudhary RK, Shukla JS. Factors influencing the yield of plateletpheresis using intermittent flow cell separator. *Clin Lab Haematol*, 2005.
- [48] Chaudhary R, Das SS, Khetan D, Sinha P. Effect of donor variables on yield in single donor plateletpheresis by continuous flow cell separator. *Transfus Apher Sci*, 2006.
- [49] Love E, Pendry K, Hunt L. Analysis of pre and post donation haematological values in plateletpheresis donors. *Vox Sang*, 1993.
- [50] Lewis SM, Anderson NA, Pamphilon DH. Comparability of haematological and biochemical parameters before and after apheresis of volunteer donors. *Vox Sang*, 1991.
- [51] 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.

- [52] Chaudhary R, Sekhar DS, Agarwal P, Shanker SJ. Quality systems in automated plateletpheresis in hospital based blood transfusion service in North India. *J Clin Apher.* 2005.
- [53] Lazarus EF, Browning J, Norman J, et al. Sustained decreases in platelet count associated with multiple, regular plateletpheresis donations. *Transfusion.*