



PLASMA APHERESIS PROCEDURE

Ajit Pal Singh	Assistant Professor, Department of Medical Lab Technology, SAHS Sharda University, Greater Noida, U.P.
Dr.Sumeet Bhargava	Prof of Radiology, GSM Medical college and Hospital, Hapur road, Pillikhwa, Hapur
Dr. Rahul Saxena	Professor, Department of Biochemistry, SAHS Sharda University, Greater Noida, U.P
Dr. Suyash Saxena	Assistant Professor, Department of Biochemistry, SAHS Sharda University, Greater Noida, U.P.

ABSTRACT

The present study investigates to prepare single donor Plasma Apheresis product in the blood center with the help of Fresenius Cell Separator for use in patient who require coagulation factors, covid patients, dengue patients etc. Apheresis is a medical procedure that involves removing whole blood from a donor or patient and separating the blood into individual components so that one particular component can be removed. Apheresis is a medical procedure that involves removing whole blood from a donor or patient and separating the blood into individual components so that one particular component can be removed. The remaining blood components then are re-infused back into the bloodstream of the patient or donor.

Apheresis is also called pheresis or hemapheresis. The terminology used may also reflect the component of blood that is being removed, such as:

- Plasma (plasmapheresis)
- Platelets (plateletpheresis)
- Leukocytes (leukapheresis or leukopheresis)
- Lymphocytes (lymphopheresis or lymphapheresis)
- Red blood cells
- (erythropheresis)

Total plasma exchange (removal of plasma and replacement with fresh frozen plasma) can also be performed using the apheresis procedure. It is also used for the collection of stem cells from the peripheral blood.

KEYWORDS

Plasma Apheresis, medical procedure, hemapheresis, Leukocytes

*Corresponding Author **Dr. Ajit Pal Singh** Asst Professor, Dept. of Medical Lab Technology, SAHS Sharda University, Greater Noida, U.P., India

1 - INTRODUCTION

Purpose:

- To prepare single donor Plasma Apheresis product in the blood center with the help of Fresenius Cell Separator for use in patient

Scope:

- The single unit of Plasma apheresis of high dose minimizes the exposure of multiple donors & maximize the benefits of the particular blood component to the patient.

Responsibility:

- Trained technical / medical personnel under the supervision of Consultant who is responsible for the smooth conduction of procedure

Location:

- Apheresis Room

II - METHODOLOGY

Material used

- Single needle closed system Fresenius Kabi kit
- Material for phlebotomy. Please refer to the procedure No 3 & 4
- EDTA (lavender top) vacutainer for product sampling
- Tube sealer
- Oral calcium tablets
- Emergency medicine tray

Activity

Principle

1. The apheresis procedure is based on the principle of dual step centrifugation based on the specific gravity of blood component

2. Single needle plasma apheresis on comtec is a single arm procedure where in blood is drawn and returned back through the same venous access. In spite of single arm procedure, the separation is continuous flow.

3. The procedure takes place in the form of cycles, the inlet cycle and the return cycle.

4. During the inlet cycle, whole blood is drawn from the donor and separated in the centrifuge compartment. 40% of the drawn blood goes into the reservoir bag. During the Return cycle, red cell and plasma are returned back to the donor and the blood in the reservoir bag enters the centrifuge compartment for separation, thus maintaining continuous flow separation.

5. Plasma are retained inside the collection container of the machine and the remaining blood is return back to the donor.

Prerequisites:

6. Selection of donor

- Properly screened healthy donor is selected for donation. Donor selection follows the standard blood donation criteria.
- Maximum 400 ml of plasma product can be removed depending on body weight which is more than 60kg
- Interval between apheresis donations should be at least 48 hours and donors should not undergo apheresis more than twice in a week or more than 24 times in a year.
- If the donor donates a unit of whole blood or if it becomes impossible to return the donor's red cells during previous apheresis, at least three months.

- Donors who have taken aspirin containing medications within 72 hours of donation should not be accepted as an apheresis donor
- He should not be fasting prior to the procedure, however, should refrain from oily/fatty food
- A prominent and easily accessible antecubital vein on one of the arms is selected for the apheresis.
- For routine apheresis the donor is tested for the Transfusion transmitted infection disease a day prior to the procedure by ECI/ELISA and should be negative.
- Test for total protein level and should be more than 6.0gm/dl and other CBC Level are within the normal limit. Platelet count should be more than 1,50,000
- Perform blood group of patient and donor should be same.
- For urgent apheresis a signed consent form from treating doctor and patient for rapid (two different kit) screening must be taken
- Other donor parameters such as Hematocrit, Height, and Weight are required to be entered into the machine. Weight should be more than 60kg
- Informed written consent is taken from the donor

iii. MODELING AND PROCEDURAL EXPLANATION Plasma Separator



Procedure

Press Power On through I switch in front panel.
Screen will display, showing software version. PRESS CONTINUE.



Following screen will display. Use up/down arrow key to select PLATELET DONATION and PRESS OK.

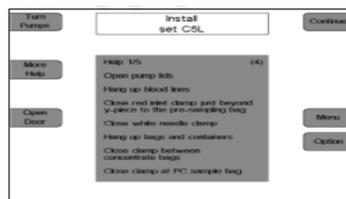


Select PLT-S5L program by using up/down keys and PRESS OK.



KIT INSTALLATION

INSTALL SET will display. Follow the Help instructions on the screen on total 5 screen pages as below.



- Open All 4 pump lids.
- Hang up blood inlet/return lines on right side IV rack hooks of cell separator.
- Close RED inlet clamp just beyond Y piece to the pre sampling bag.
- Close WHITE needle clamp.
- Hang up storage Platelet Bags at left side of device, Close clamp between 2 platelet concentrate storage bags.
- Close Clamp at Platelet concentrate sample bag.
- Hang empty bag at hook above return drip chamber.
- Hang Plasma bag at hook above clamp 4.
- Install all 4 pump segments by inserting the top pump adapters to colour coded pumps, hold with fingers and PRESS TURN PUMPS. PUMPS will be loaded automatically. Close PUMP LIDS to all 4 PUMPS.
- Install the RETURN DRIP CHAMBER at the AIR DETECTOR in such a way that DRIP CHAMBER is equally outside the DETECTOR on both TOP/BOTTOM side of DETECTOR.
- Install the plasma line in clamp 4 between the Y-piece and drip chamber.
- Install the plasma line section marked by the yellow tabs into the Hb/Hct detector.
- Insert the line leading to the empty bag in clamp 5.
- Insert the return line in clamp 1.
- Insert the inlet line of the cell pump into the cell detector.
- Install the drip chamber of the ACD line, which is identified by a green clamp, in the ACD detector and pull the drip chamber completely down.
- Install the pump adapter for the ACD pump. The threading pin for the ACD pump must be in the 5 o'clock position. If this is not the case prior to installing the adapter, press the Turn Pumps key. Pump will be automatically loaded
- Install the two saline lines in clamp 2 and clamp 3. Make sure that the lines are installed so that their colour matches the colour coding of the covering foil and the colour of the roller clamp (red line clamp 2, blue line Clamp 3).
- Screw the filters of the red-coded pressure measuring lines for the inlet pressure onto the red-coded pressure measurement port for the inlet pressure.
- Screw the blue-coded pressure measuring line for the return pressure onto the blue-coded pressure measurement port for the return pressure.
- Hold the separation chamber at the upper centrifuge adapter and let it hang down freely beside the device to avoid twisting of the line.
- Open the hinged door of the chamber holder. Push the circular adapter of the separation chamber into the groove in the central funnel. Close the hinged door until it locks into place. The locking pin

on the flat side of the chamber holder must no longer be visible.

w) Remove the empty packaging from the centrifuge door. Press the Open Door key. Slide the centrifuge door open. If Open Door is not displayed, the door cannot be opened.

x) Turn the centrifuge rotor until one of the two line guides is on the right of the rotor. Push the chamber holder with the installed separation chamber under the rotor with the lines pointing down.

y), Push the chamber holder onto the guide rail until it is felt to be locked. Swing the locking flap down until it clicks into place. Pass the centrifuge tubing through the line guide.

z) Push the upper centrifuge adapter narrow side first into the upper adapter holder. Should it be necessary to slightly turn the adapter, then turn it in the direction in which the individual lines are twisted around one another. After a test revolution and another visual check, close the centrifuge door. The door is properly locked, when the Open Door key is displayed. Place the Air Protect in the holder.

Caution Ensure that the centrifuge tubing is not trapped between chamber holder and rotor.

Note Manually turn the rotor one full revolution counter-clockwise to verify correct installation.

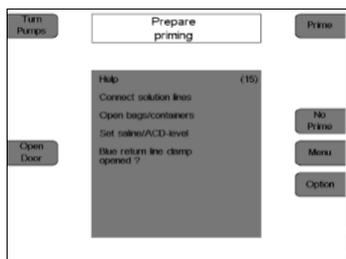
Checks After Apheresis Set and Separation Chamber Installation Visually verify the following:

- The red clamp on the inlet line below the branch to the resampling bag, the white needle clamp, the clamp between the concentrate bags and the clamp on the concentrate sampling bag must be closed.
- All other stop clamps on the set must be open.
- The separation chamber must be correctly installed.
- The drip chamber in the air detector and the ACD-A drip chamber must be correctly installed in their holders.
- The ACD-A pump adapter and the ACD-A line must be correctly installed in the ACD-A pump below the drip counter.
- The return line is installed in clamp 1. The saline lines must be inserted in clamp 2 and clamp 3.
- The plasma line must be installed in clamp 4.
- The line leading to the empty bag must installed in clamp 5.

Preparing for Priming:

PRESS CONTINUE; Following screen will display.

- Prior to priming the set, a user guide is available to assist with the connection of the saline and ACD-A solutions.
- Connect the ACD-A bag to the green connector and hang it from the upper left hook on the front of the device.
- Break the cone of the ACDA bag. Deaerate the ACD-A drip chamber by pressing it and set the level to approximately 1 cm, so that the fluid level is approximately 1 cm below the optical sensor.
- Connect the saline bag to the two transparent connectors. Hang the saline bag from the front left hook.
- Break the cones and set the fluid level in the two drip chambers.



START PRIME by PRESSING PRIME KEY. During priming saline and ACD-A will be pumped into the set to displace the air and check as follows automatically. In case of any error in loading an alarm will be displayed with help screen available for the same error.

i. First ALARM test will be performed by the machine automatically. After the alarm test, PRESS CONTINUE to start PRIME.

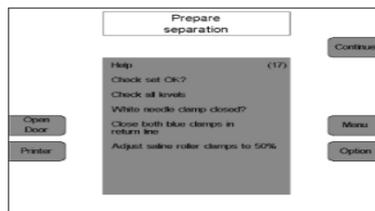
ii. RE PRIME can be done by selecting the PRIME key again after the

completion of AUTOMATIC PRIME. PRIME takes around 6 minutes to complete.

iii. At the end of PRIME, PRIME SALINE DIVERSION can be selected by using UP/DOWN keys to DONOR or to WASTE BAG.

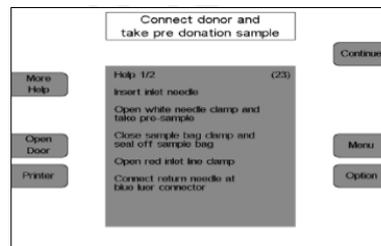
Preparing for Separation:

- Visually check the apheresis set. Check and, if necessary, adjust the fluid level of the connected solutions in all drip chambers. Check that the white needle clamp is closed and close, if necessary. Close the two blue return clamps. Set the roller clamps to 50%. Press the Continue key.



Connecting the Donor and Collecting a Pre-Donation Sample

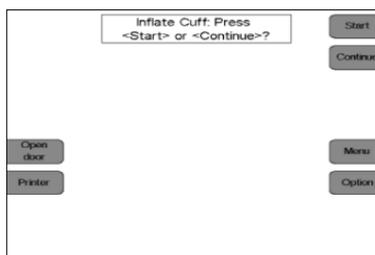
- Place the inlet needle. Open the white needle clamp and collect a pre-donation sample of at least 20 ml. Close the clamp on the pre-sampling bag and seal off the pre-sampling bag. Open the red clamp on the inlet line and check that the two red clamps are open.
- Connect the return needle to the blue Luer lock connector. Deaerate and place the return needle. Open the blue return clamp.
- Press the Continue key.



Applying the cuff

- Apply the cuff to the fully extended and relaxed upper arm of the donor. It must be ensured that the cuff contains no air; this is done by opening the red deflation valve on the air-pressure pump and by pressing the cuff with your hand to remove all air.

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 mmHg. A subsequent adjustment can be made by turning the scale.

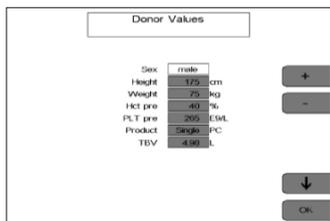


- Connect the cuff to the cuff port on the rear connector panel and ensure that the connecting line is not squeezed or kinked.
- By pressing the Start key, the cuff is inflated up to a pressure of approx. 50 mmHg to facilitate puncturing of the donor. Due to its design the pump has a maximum pressure of 100 mmHg. The Inflate cuff display can be skipped by pressing the Continue key.

Menu

Donor Values: In this screen the donor values (height, weight, etc.) must be entered with the up, down, + and – keys. After entering the data, press the OK key. The software calculates the maximum possible blood flow based on the ACD rate and the donor values set in the Config.sys.

The calculated values will be displayed in the Procedure Menu screen.



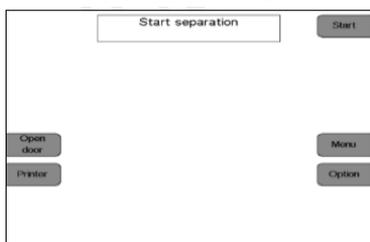
Procedure Menu:

Select the value to be altered with the up and the down keys. Use the + and – keys to alter the selected value. All values affected by this change will be automatically adapted. A change of the yield will, for example, result in an automatic recalculation of the blood volume to be processed.

PRESS OK; ALL VALUES WILL BE SAVED.

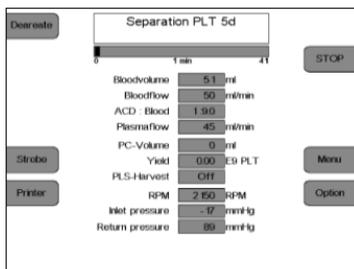
Separation:

All separation parameter changes should be made before starting the program, but can also be made at a later stage.



PRESS START: Press the Start key. The device automatically performs a system pressure test to check the pressure measuring lines for tight connection and to verify correct position of all clamps at the return drip chamber.

Automatic operation:



- Process will be fully automatic till the target volume is processed. Separation can be STOP in between; also use DEAREATE for starting donor SALINE to keep the veins patent. Additional Plasma can be collected, if desired by selecting Program Menu and Configuration .sys. Enter desired PLS volume to be collected. Separation can be started again by START key. Procedure can be terminated any time in between, by Going to OPTION and Selecting DIRECT REINFUSION Followed by OK at any time.
- Inflow phase: At the beginning of the separation program, blood is delivered into the chamber at a low speed (1000 rpm) The blood flow is reduced at this moment. The plasma flow is by 10 % lower than the blood flow. As soon as the interface detector detects blood in the separation chamber, or after delivery of 30 ml plasma, the centrifuge speed will be increased to the set point calculated for the separation and the interface continues to develop. As soon as the interface has developed, the inflow phase is terminated and the flow of the whole blood pump is gradually increased to the desired flow. On completion of the inflow phase separation is continued in the automatic operation mode. Since the interface usually collapses after a stop condition, separation is always started with an inflow phase each time it is restarted. The speed of the centrifuge will then, however, not be reduced. If the stop condition lasts longer than 30 seconds, the centrifuge speed is reduced to 1000 rpm.

- Collection cycle: During the collection phase, the processed blood is delivered into the SN bag. At the beginning of the collection phase, the cuff is inflated to a pressure of approx. 50 mmHg. This slightly compresses the donor's vein to avoid possible flow problems. While the cuff is being inflated, the blood flow is reduced by 20%.
- At the end of the last collection phase of a standard separation procedure, the total extracorporeal volume amounts to 230 ml (set) + 150 ml (SN bag) + 250 ml (platelet concentrate bag) = 630 ml (incl. ACD). It is at the discretion of the attending physician to decide whether this volume is tolerated by the donor. The extracorporeal volume can be altered in the by reducing the SN cycle volume Config.sys. In the first collection phase an approx. 80 ml buffer will be delivered into the SN bag in addition to the preset collection volume (volume buffer). This buffer prevents blood with a low haematocrit from entering the separation chamber which would cause a reduction of the interface (the haematocrit in the upper part of the SN bag drops due to sedimentation of the platelets during collection). If the last collection phase of the COM.TEC is less than 50 ml, the collection phase preceding the last collection will be increased up to a maximum of 50 ml and automatically becomes the last collection. Return cycle The volume of blood delivered to the SN transfer bag during collection (= cycle volume) is returned to the donor by means of the whole blood pump by reversing clamp 3 and clamp 6. The blood is thus passes once again through the separation chamber. The final return is automatically terminated when the volume of blood collected in the SN bag during the collection has been completely returned to the donor.
- Return blood flow: The return blood flow can be set in the Procedure menu. The separation time can be reduced by increasing the return blood flow. The ACD infusion rate during this phase will then increase. It is at the discretion of the attending physician to select an adequate return blood flow. The return blood flow is coupled to the collection flow. The maximum difference which can be set is 10 ml/min. In the default setting the return blood flow is 5 ml/min higher than the collection flow. Depending on other settings the program will only allow for certain maximum flow rates. When the maximum flow has been reached, the associated key will no longer be displayed.

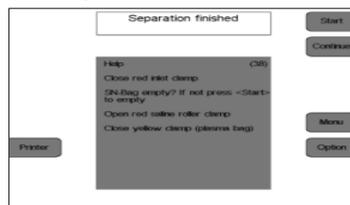
Changing options

Use the UP and the DOWN keys to select the parameter to be changed. Use the + and the – keys to change the selected parameter. Press the OK key to confirm the change.

Options

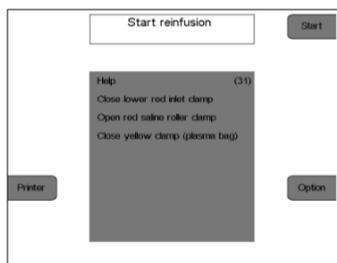
- Print parameters Prints the parameter list
- Direct reinfusion -Controls the saline diversion at the start of the separation
- Cuff SN -Controls the automatic cuff
- Chime SN -Controls the audible signal when switching from collection to return and vice versa
- Exit program -Terminates the program prematurely. When the standard program is used, e.g. with a donation time of approximately 80 minutes, the ACD load to the donor is approx. 375 ml ACD. This corresponds to a mean ACD rate of 4.7 ml/min. Since no fluid is infused to the donor during the collection phase, the maximum ACD
- Completing the separation program: When the target yield has been achieved the separation will be terminated automatically.
- Empty SN-Bag:

If the SN bag is not empty, SN return can be continued for another 20 ml each time the Start key is pressed. Emptying of the SN bag can be stopped at any time by pressing the STOP key. If the SN bag is not empty, SN return can be continued for another 20 ml each time the Start key is pressed. Emptying of the SN bag can be stopped at any time by pressing the STOP key.



Reinfusion:

AT the end of processing Target volume Display will show SEPARATION FINISHED. Press CONTINUE, Following Reinfusion start menu will be displayed as following:

**Follow the instructions on display as follows:**

1. Close the lower red inlet clamp.
2. Completely open the red roller clamp of the saline line.
3. Close the yellow clamp on the plasma collection bag.
4. Disconnect the donor from the inlet line.
5. Press the Start key.

You can terminate Reinfusion pre mature, if desired by selecting OPTION and EXIT REINFUSION followed by OK key.

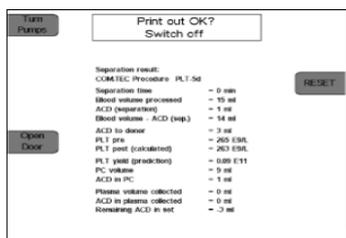
END OF REINFUSION:

- I. Close the stop clamp of the return line.
- ii. Close the yellow stop clamp of the plasma bag.
- iii. Press the Continue key. Disconnect the donor.
- iv. Press the Continue key.
- v. Deaeration of Concentrate Bags and Collection of Samples
- vi. Deaeration of concentrate bags

- The deaerating option is only available if the menu option F PC deaerate in the Config.sys has not been deactivated. Display Use forceps to clamp both the red blood cell line leading to the drip chamber and the whole blood line below the air separator. Remove the cell pump line segment from the pump. Remove the concentrate bag, holding its connector up. Press the Start key. The concentrate bag is being deaerated. As soon as the concentrate bag is completely deaerated, press the STOP key. If the concentrate bag has not yet been completely deaerated, press the START key to remove another 5 ml of air. On completion of the de-aeration, press the STOP key.

REMOVING PLASMA BAG AND SET

- Seal off the concentrate bag and remove the set.
- Press the Continue key.
- After the report has been printed, the device can be started for another separation by pressing the RESET key.



- Report will be printed as above on the Printer. TURN the device OFF by O key.

Collection of Concentrate Samples

- On completion of reinfusion thoroughly mix the concentrate in the open concentrate bag.
- Allow the concentrate bag to rest for 1 h.
- Collect the sample. To obtain a representative sample, the lines must be sufficiently rinsed with platelet concentrate before collecting the sample.
- Touch "Continue" so that machine begins "Prime".

I. Once prime is complete, the screen instructs to enter Parameters.

ii. Touch "Estimator" button on the menu screen.

iii. Select each of the following parameters and enter the donor values: Precount, Haematocrit, Height, Weight, Gender, Desired Yield, Plasma Product, ACD ratio, Citrate infusion rate, Storage fluid.

iv. The Values are entered using the keypad on the screen, which appears after the parameter button is touched. Touch "Accept" after entering the correct value.

v. Touch "Transfer Parameters" to enter all the values into the procedure.

vi. Touch "Continue" on the Enter Parameters screen.

vii. Touch "start needle prime" and open the roller clamp on the inlet / return line to flush the needle. In case, a blood sample is to be collected, prime the line only up to the Y junction

viii. Perform venipuncture on the donor. Non- anticoagulant added blood could be collected, if required, from the sample pouch attached to the line. Cuff pressure button can be used to provide pressure on the arm.

ix. Open the roller clamp completely and check for the free flow of saline to confirm potency and rule out extravasations.

x. Touch "Begin Collection" button followed by the "Yes" button to confirm the initiation of collection.

xi. Monitor for any adverse effects of ACD. Give oral Calcium tablets to the donor to minimize any untoward effect. Provide pressure on the inlet line, if required, using the Cuff Pressure button.

xii. Once the target Whole Blood to process is achieved, a note of "Perform Reinfusion" is displayed on the screen. Acknowledge the note to confirm the start of reinfusion.

xiii. Close the roller clamp on the inlet line and touch Continue. Reinfusion will begin. During his time, remove the inlet line and free one arm of the donor.

xiv. Once Reinfusion is over, Procedure Wrap-up screen appears along with a note of "Remove Needle".

xv. Touch "remove needle" and disconnect the donor by closing the roller clamp on the line and removing the needle

xvi. Touch "Transfer Product" and open a clamp on one of the plasma storage containers. Touch Continue.

xvii. Open the centrifuge compartment and remove the collection pack, as instructed by the display.

xviii. Touch "Continue" and thoroughly suspend the Apheresis product.

xix. Hang the collection pack on the right front scale hook without disturbing the scale and touch "Continue". The plasma will be transferred into the storage bag.

xx. When the note on screen says "Product Transfer Complete", acknowledge the note and close the clamp on the filled storage container. Also close all the other clamps of the kit.

xxi. Touch "Remove Kit" on the screen. Remove the kit and touch "Continue".

xxii. The screen will display Procedure Result.

xxiii. Using a sealer, seal off the product bag and detach it from the rest of the kit.

xxiv. Release the donor from the apheresis room after confirming that he is stable and bleeding from both the venipuncture sites has stopped.

xxv. Transfer the product sample into an EDTA tube.

xxvi. Document all the details of the procedure including all the alarm/reaction as well as the QC results.

Complications during Apheresis

Hypotensive reactions

- Can occur due to intravascular volume depletion, vasovagal reactions, citrate toxicity, severe allergic reaction, and air embolism.
- Sign and symptoms of vasovagal reactions are lightheadedness, hot flashes, pallor, diaphoresis, nausea, vomiting decreased heart rate, and decreased blood pressure.
- Most likely occur with first time apheresis donors due to anxious behavior about procedure.

Prevention and Management of donor reaction

- Pause the procedure, lowering the head and raising the feet, applying the cold compression to the forehead and neck and reassuring the donor.
- Infusion of intravenous fluid and return of blood within the extra corporeal circuit

Citrate reactions

- Most common adverse effect with apheresis procedure.
- Results from ionized hypocalcemia due to infusion of citrate anticoagulant given at the time of procedure.
- Common Symptoms include nausea/vomiting progression of paresthesias to the hand, feet, throughout body, chills, abnormal cramping, lightheadedness or hypotension
- Severe Symptoms include painful muscle cramps, tetany, blurred or double vision, loss of consciousness cardiac arrhythmia and seizure.

Prevention and Management of donor reaction

- Reducing the return rate of the instrument, pausing the procedure to allow the donor to metabolize some citrate and release bound calcium.
- Administration of oral calcium carbonate or in severe cases intravenous calcium solution.

Hematoma and Infiltration

- It can occur at any time during procedure due to venous access failure
- Acute complications include hematoma, infiltration, thrombosis.
- Symptoms include pain and/or pressure and bruising and/or swelling at the needle site.

Prevention and Management of donor reaction

- Discontinuing the collection procedure, removing the needle and applying pressure to the site.
- Cold-compression may be used to relieve donor
- Ensuring the donor to be well hydrated before procedure and kept the needle site secure and stable.

Loss of Consciousness and seizures

- Very common and usually occur as a result of vasovagal reaction or severe citrate toxicity.
- It accompanied by tonic-clonic jerking (does not represent true seizure)

Prevention and Management of donor reaction

- Discontinuing the collection procedure, lowering the head and raising the feet

Records:

Maintain the record on apheresis procedure record sheet

IV - Conclusion:

Apheresis is a nonsurgical treatment in which a component of blood, such as plasma or red blood cells, is removed or replaced. Removal and/or replacement of these components can be used to decrease or prevent worsening of disease in a patient.

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