ORIGINAL RESEARCH PAPER

Volume-7 | Issue-12 | December-2018 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

INCIDENCE OF ADVERSE EVENTS ASSOCIATED WITH PLATELETPHERESIS : PROSPECTIVE STUDY IN A REGIONAL HOSPITAL.

Medical Science

Dr Mitali Sharma Post-graduate; Department Of Blood Transfusion And Immunohaematology

Dr Ankur Malhotra* Senior Resident; Department Of Medicine *Corresponding Author

ABSTRACT

INTRODUCTION: Plasmapheresis is usually well tolerated. Occasionally, Adverse Events (AEs) of variable severity may occur during or after the procedure. AEs that occur in Donors are divided into local reactions and systemic reactions.

MATERIALS AND METHODS: A total of 57 apheresis procedures were performed in a period of one year study. All the adverse reactions occurring during this period were documented.

RESULTS: All the donors in our study were male. Out of 57, 5 suffered adverse reaction. The incidence of adverse effects was 8.77% in our study. None of these reactions was life threatening and none of the procedure was needed to be halted in between because of them.

CONCLUSION: Plateletpheresis procedures performed on cell separator are safe, with a low incidence of significant AEs.

KEYWORDS

Adverse events, citrate reaction, ACD- acid citrate dextrose solution.

INTRODUCTION

The key forces driving Transfusion Medicine into the 21st century are safety and quality, availability of blood, legal and regulatory issues and cost. The issues of safety and quality of blood and blood products are enhanced with use of Apheresis derived products. Metered anticoagulation, automation during collection, reduced variables and fewer donor exposures enhance safety and quality of the Apheresis procedures. [10]

Plateletpheresis procedures are usually well tolerated procedure. Adverse Events (AEs) of variable severity may occur during or after the procedure. AEs that occur in donors can be divided into local reactions and systemic reactions.[8,13]

Local reactions are usually haematomas due to extravasation from the veins, caused by incorrect placement of the needle during the venipuncture. Pain, hyperaemia and swelling may develop at the site of the extravasation. Local phlebitis and thrombophlebitis are very rare.[2,12]

Systemic reactions are mainly vasovagal reactions that can be triggered by the pain of the venipuncture, or by the anxiety and state of tension of undergoing the donation, etc. These are characterised by the pallor, sweating, dizziness, nausea, hypotension, bradycardia, and syncope. Citrate toxicity occurs because of the use of acid-citrate-dextrose (ACD) in apheresis.[4,12]

The intravascular volume deficit during the procedure should not exceed 10.5 mL/kilogram of the donor's weight. Plateletpheresis units must contain 3.0 $X10^{11}$ or more platelets per unit in at least 75% of the units tested at maximal storage time. The physician in charge of the donor apheresis unit can make a medical decision to accept a donation from someone not eligible at the time if the benefits to the intended recipient outweigh the risks to the donor. (Rossi's Principles of Transfusion Medicine, fourth edition)[12].

The cell separators can yield high dose plateletpheresis, resulting in up to four units of apheresis platelets for transfusion to patients. However, concerns regarding the safety of platelet donors run contrary to these interests and technical possibilities. Although many undergo plateletpheresis but the data on consequences of plateletpheresis for donor's health is limited. Hence, this study was taken up in our hospital to find out the incidence of reactions during and after plateletpheresis procedures.

MATERIALAND METHOD

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

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

Some other specific donor selection criteria for plateletpheresis included:

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

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

A. Pre-donation activities:

- Written consent for the plateletpheresis procedure by the treating consultant were checked
- Donor questionnaires were filled up and answered by the donors.
- The age and weight of the donors were noted
- Medical examination of the donors was done
- The donors were checked for good venous access in both arms and the arm with better venous access was chosen for the procedure.
- Written Consent of the donors were taken after explaining the procedure to the donors in the language understood by them.
- Screening for Transfusion Transmitted diseases were done for HIV, HbsAg, VDRL, HCV, Malaria using rapid kits

B. Activities related to Donors;

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

C. Procedure:

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

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

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

D. Post-donation activities include:

- Examination of the vitals e.g. BP, pulse, Respiration.
- Any discomfort to the donor during the procedure was documented. Any adverse reaction if occurred during or after the procedure was properly reported.

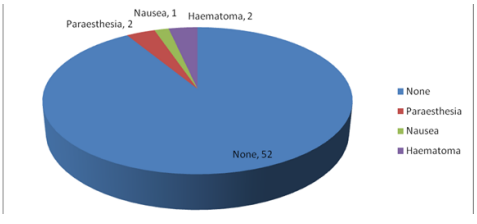
After the procedures were complete the bags were kept at room temperature for 1 hour and then were stored in the Platelet Agitator Incubator. Visual check of the products was done before issuance.

RESULTS

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

All the donors were above 18 years of age. Range was 19 to 54 years. Maximum no. of donors were in age group of 29-38 years with mean of 35.14 ±8.31 years and median of 34 years. Maximum number of donors had weight between 70-79 kgs. No donor had weight less than 60 kgs. The mean weight of the donors was 75.33± 9.81 Kgs while its median was 73Kgs.

Out of total of 57 donors that donated for Apheresis, 8.77 %(n=5) experienced adverse effects during the procedure. 2 (3.51%) donors experienced mild tingling around mouth, 2 (3.51%) developed haematoma at the site of venepuncture, and 1 (1.75%) suffered from nausea. None of the procedures needed to be stopped in between because of the adverse effects. Out of 5donors who suffered reaction, 4 donors had weight less than 70 kg .



Incidence of various adverse effects.

DISCUSSION

Apheresis procedures are usually well tolerated. Adverse Events (AEs) of variable severity may occur during or after the procedure. As the blood donor pool is unable to keep pace with the growing blood transfusion requirements, the transfusion specialists are trying to utilize each donor maximally [12]. This has led to a trend in the increasing use of automated blood collections. These collection methods share many of the same reactions and injuries seen with whole blood donation but also have unique complications due to the collection method and the frequency at which donation can occur. Overall, evidence in the literature suggests that the frequency of reactions to apheresis donation is less than that seen in whole blood donation. [9]

The most common Apheresis specific reaction is hypocalcemia due to citrate anticoagulant used, which even though usually causes mild reaction, has potential of several reaction in the donor. Other reactions to Apheresis are comparatively uncommon like hypotension or rare (e.g. air embolism).

Many studies have shown safety of plateletpheresis procedures and lower rate of adverse effects associated with them (Mcleod et al.1998; Yuan et al. 2008; Croco et al. 2009;.Philip et al 2013). **In** our study 5 donors i.e. 8.77% experienced adverse reaction. 2 (3.51%) donors experienced mild tingling around mouth, 2 (3.51%) developed haematoma at the site of venepuncture, and 1 (1.75%) suffered from nausea. None of the procedures needed to be stopped in between because of the adverse effects[8,9,14].

The most common recorded adverse reactions occurring due to plateletpheresis procedures are citrate related. Citrate comes from the ACD-A, which is used as anticoagulant in these procedures. Citrate chelates calcium ions and can cause symptoms like peri-oral tingling sensation, paresthesias etc. however they are transient and self resolving.

Garcia et al. documented that female sex and low weight acquired predictive value with respect to the occurrence of adverse effects[7]. Farrokhi et al. suggested a protocol for step-down decrease in ACD-A infusion during Apheresis to reduce the rates of adverse reactions during plateletpheresis due to citrate toxicity[6]. McLeod et al also reported the incidence of adverse events during plateletpheresis procedure and did not document any serious adverse effect. Pain or haematoma at the site of venipuncture was the most common adverse effect reported; however mid paraesthesias were excluded from the study.citrste induced nausea and vomiting occurred in 0.8% of the donors. They concluded that Plateletpheresis is a safe procedure[8].

Das et al. studied changes in serum calcium and magnesium during and after Apheresis and reported statistically significant drop in levels of both. However, no donor experienced any adverse reaction[5].

Yuan et al. reported that moderate to adverse effects occurred in 0.47% of Apheresis donations. Vasovagal reactions constituted 96.2% of these. They also observed significantly low pre-donation total blood volume and haematocrit and high total RBC loss and net fluid loss in these cases that experienced adverse effects[14]. Croco et al. (2009**)** also concluded that the incidence of adverse effects is very low in Apheresis donations. Citrate toxicity was reported in association with 0.38% (189/50,072) of apheresis donations[3]. Philip et al reported that the rate of vascular injury (VI), Citrate reaction (CR), and Presyncopal/Syncopal (PS/S) in plateletpheresis was 1.6% (52/3,120), 0.96% (30/3,120), and 0.096% (03/3,120), respectively. Overall, AEs for Plateletpheresis were 2.7% (85/3,120)[9]. They also suggested that the treatment of citrate reactions is relatively simple when the reactions are identified early. The treatment includes slowing the re-infusion rate to allow for dilution and metabolism of the citrate, increasing donor blood to citrate ratio to decrease the amount of citrate infused, giving oral calcium supplement, and if required giving intravenous calcium. These studies are in agreement with our findings also. Hence plateletpheresis is considered as a safe procedure with very small risk of life threatening adverse effects.

CONCLUSION

The incidence of adverse effects was 8.77% in our study. None of these reactions was life threatening and none of the procedure was needed to be halted in between because of them. Apheresis donations performed on cell separators are safe, and have acute reaction rates less than those seen with whole blood donations. The acute effects of donation are relatively mild and easily treated. Recent evidence suggests, however, that repeated apheresis donation may produce adverse long-term effects in donors such as bone demineralization and cataract formation.[2 Additional research is needed to ascertain the risks of

long-term apheresis donation In conclusion, it can be said that, plateletpheresis is a safe procedure for healthy donors.

REFERENCES

1. AABB technical manual 17 th edition C h a p t e r 7 Blood Component Collection by Apheresis .pg 228-230
2. Brecher ME, Leger RM. AABB technical manual. 15th ed. Bethesda: American Association of Blood Banks; 2005
3. Crocco I, Franchini M, Garozzo G, Gandini AR, Bonomo P & Aprili G. Adverse reactions in blood and apheresis donors: experience from two Italian transfusion centres. Blood Transfus. 2009; 7(1): 35-8
4. Crookes RL, Hillyer CD. Blood banking & transfusion medicine. 2nd ed. Philadelphia: Churchill Livingstone; 2009.
5. Das SS, Chaudhary RK & Shukla JS. Factors influencing yield of plateletpheresis using intermittent flow cell separator. Clin Lab Haematol. 2005; 27: 316–319
6. Farrokhi P, Farahmand H, Bismuth A, Suarez C, Ducot B, Gillon MC et al. How to stabilize the level of ionized calcium and citrate during plateletpheresis. Vox Sang. 1998; 74(1): 7-12
7. .Garcia Gala JM, Rodriguez-Vicente P, Martinez Revuelta E, Alonso Garcia A, Sanzo Lombardero C & Alvarez Ferrando A. Complications of plateletpheresis procedures. Sangre (Barc). 1998; 43(5): 365-70
8. Mcleod BC, Price TH, Owen H, Ciavarella D, Sniecinski I, Randels MJ, et al. Frequency of immediate adverse effects associated with apheresis donation. Transfusion. 1998;38:938–43.
9. Philip J, Sarkar RS, Pathak A. Adverse effects associatecd with apheresis procedures: Incidence and relative frequency. Asian J Transfus Sci. 2013; 7(1): 37-41
10. Roback J, Combs MR, Grossman BJ & Hillyer CD 2008 Technical Manual 16th Edn, American Association of Blood Bank (AABB), Bethseda, Maryland
11. Rossi's Principles of Transfusion Medicine, fourth edition. Chapter 41: Apheresis: Principles and Technology of Hemapheresis. Pg622-624
12. Simon TL, Dzik WH. Rossi's principles of transfusion medicine. 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2009
13. Winters JL. Complications of donor apheresis. J Clin Apher. 2006;21:132–41.
14. Yuan S, Gornbein J, Smeltzer B, Ziman AF, Lu Q & Goldfinger D. Risk factors for acute, moderate to severe donor reactions associated with multicomponent apheresis collections. Transfusion. 2008; 48(6): 1213-9.