ORIGINAL RESEARCH PAPER

Transfusion Medicine

ADVERSE EVENTS ASSOCIATED WITH PLATELETPHERESIS: A PROSPECTIVE STUDY FROM A TERTIARY CARE HOSPITAL.

KEY WORDS:
Plateletpheresis, donor reaction, citrate toxicity, vascular injury

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ABSTRACT

Plateletpheresis is used to obtain platelets from volunteer donors, patient's family members,or donor with HLA or platelet antigen compatible phenotypes. **Aim:**To analyze the adverse reactions due to single donor plateletpheresis. **Materials and Methods:**This was a prospective observational study conducted over a period of one year from September 2018 to August 2019 in the department of Immunohematology and Blood Transfusion Medicine, GMC Jammu. A total of 157 plateletpheresis procedures were performed after taking informed and written consent from the donor. The donors were selected as per the guidelines of Director General of Health Services (DGHS). Single arm procedure was used.All the procedures were performed on Fresenius kabiCom.tec op 5/07.08 by intermittent flow centrifugation (IFC). The adverse events (AE's) were classified as donor related and kit/equipment related. **Results:** A total of 10 AE's were noted of which 6 (60%) events were associated with donors and 4 (40%) events were owned to fault in the kit/equipment.Donor related 6 AE's include citrate toxicity[n=3(50%)], vasovagal reactions [n=2(33.33%)] and hematoma [n=1(16.67%)].Machine related 4 AE's include leakage in the kit[n=3(75%)] and interface error [n=1(25%)]. **Discussion and Conclusion:** Our study showed (n=6)3.82% donor reactions and equipment related (n=4) 2.54% reactions. Apheresis donations performed on cell separators are safe. The percentage of reactions in our study was 6.36% and no serious adverse reaction was noted .But precautions and close monitoring helps to reduce such mild forms of reactions.Increasing demand of platelet transfusions for patients had led to accelerated use of Apheresis, cause of higher yield of platelets obtained from single donor.

INTRODUCTION

Apheresis is a procedure in which whole blood is removed from the body and passed through an apparatus that separates out one particular blood constituent. It then returns the remainder of the constituents to the individual's circulation. In Plateletpheresis, that one removed product are platelets.

The motivation to collect more than one product from a single donor comes from decreasing the donor pool and minimizing the risk of alloimmunization from multiple donors in the case of whole blood-derived component usage. The therapeutic dose of a component can be collected from a single donor with less volume of the product when compared to whole blood-derived components. These facts motivate both the blood collection center and the physician to shift toward the apheresis method of component collection.[1-3] Apheresis procedures are usually well tolerated, but adverse events (AEs) occur in a few cases. They may occur during or after the procedure. The overall rate of AEs with apheresis donation is approximately ten times less than that seen with pooled platelets obtained from whole blood donation, with mild events outnumbering the more severe ones, although the frequency of events requiring hospitalization may be higher in apheresis than with whole blood donation.[4] Hospitalization is still extremely rare.

AIMS AND OBJECTIVES

To analyze the adverse reactions due to single donor plateletpheresis.

MATERIALS AND METHODS

This was a prospective observational study conducted over a period of one year from September 2018 to August 2019 on eligible donors in the department of Immunohematology and Blood Transfusion Medicine, GMC Jammu. All the procedures were performed on Fresenius kabi Com.tec op 5/07.08 by intermittent flow centrifugation (IFC). A total of 157 plateletpheresis procedures were performed after taking informed and written consent from the donor. All procedures were performed following departmental standard operating procedure using closed system plateletpheresis kits and acid, citrate, and dextrose-A (ACD-A) as an anticoagulant in the proportion of 1:9–1:12. The end point of each procedure was based on target yield of 3×10^{11} platelets per unit, maintaining blood flow rate of 60–70 ml/min.

Inclusion Criteria

Donors were selected as per the set criteria for single donor platelet (SDP) preparation according to Director General of Health Services (DGHS)guidelines:

(i) Weight > 50 kg
(ii) Age - 18 to 60 years
(iii) Haemoglobin >12.5 gm/dl
(iv) Platelet count > 150 × 103/µl
(v) Negative for tti screening

Exclusion Criteria

(I) Haemoglobin <12.5 gm/dl
(ii) Platelet count <150 × 103/µl
(iii) Donated in < 48hrs
(iv) On medication like aspirin

The adverse events (AE's) were classified as donor related and kit/equipment related.

Ethical And Institutional Issues

The study has been approved by institutional ethical committee. Informed consent of the participants were collected before the start of plateletpheresis procedure.

RESULTS

A total of 157 plateletpheresis donations were performed ,all

were male donors. In our study we had 6.36% of adverse reactions.A total of 10 adverse events (AE's) were noted of which 6 (60%) events were associated with donors and 4 (40%) events were owned to fault in the kit/equipment.

Donor related 6 AE's include citrate toxicity [n=3(50%)], vasovagal reactions [n=2(33.33%)] and hematoma [n=1(16.67%)].(table 1)

Machine related 4 AE's include leakage in the kit [n=3(75%)] and interface error [n=1(25%)].(table 2)

Donor-Related Adverse Events

- Citrate toxicity manifested as perioral tingling sensation was seen in three donors. Oral mouth dissolving calcium tablets had been given to all the cases in routine to prevent hypocalcemia.
- Vascular injury was seen in one donor. Hematoma formation was seen in that donor.
- Vasovagal reaction was seen in two donors out of whom one donor had concealed history of no intake of meals in last four hours.

Kit/Equipment-Related Adverse Events

Leakage in the kit was seen in three cases and interface error was seen in one kit.

The leakage in the kit was replaced with new kits.
All the adverse events reported during the study period were of mild or moderate type, no severe reaction was reported nor hospitalisation of the donor was required. All the adverse events were managed in blood bank only.

Table 1: Donor Related Adverse Events

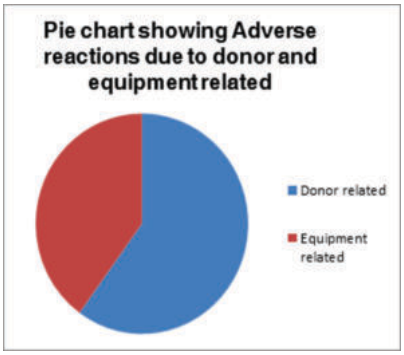
Causes	Number	Percentage
Citrate toxicity	N=3	50%
Vasovagal reactions	N=2	33.33%
Hematoma	N=1	16.67%
Total	N=6	100%

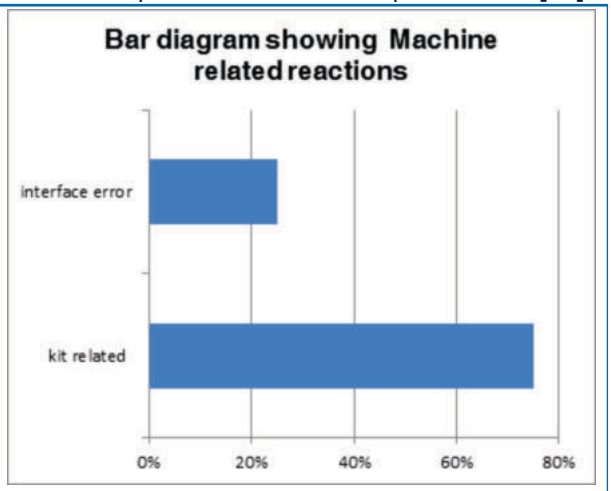
Table 2: Machine Related Adverse Events

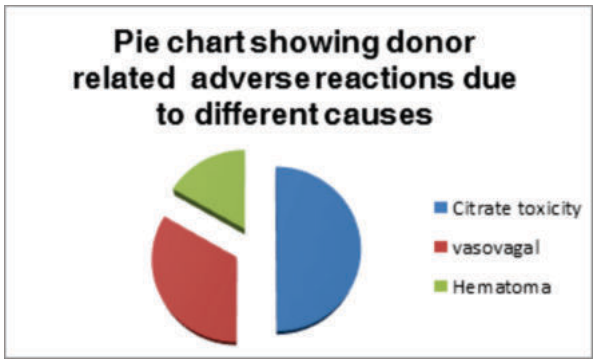
Causes	Number	Percentage
Kit leakage	N=3	75%
Interface error	N=1	25%
Total	N=4	100%

Table 3: Grading Of Vasovagal Reactions And Citrate Toxicity In Plateletpheresis Donors

Grade	Mild	Moderate	Severe
Vasovagal reactions(Signs and symptoms)	Anxiety, nausea vomiting, bradycardia, perspiration, hyperventilation, weakness, and hypotension.	Loss of consciousness or recovery period is >15 min	Tetany, convulsions, incontinence, or cyanosis with or without syncope
Citrate toxicity (Signs and symptoms)	Perioral and peripheral paresthesia, chills, shivering.	Light-headedness, muscle cramps, nausea, vomiting.	Laryngeal spasm, seizures, arrhythmia, prolonged QT-interval.







DISCUSSION

Data with regard to donor adverse effects in plateletpheresis vary from center to center despite using the modern apheresis instruments. Donor demographic and physiological profiles probably play important roles in determining such adverse effects.[5,6,7] These reactions and injuries are usually transient and self-limited. In very rare exceptions, a donor may sustain permanent damage. These reactions are unpleasant for donors, complicate collection process, decrease chance of obtaining a full unit of (single donor platelets) SDP, require treatment and monitoring of donors, and are a significant disincentive for repeat donation.

The adverse reaction rates in various studies were ranging from as low as 0.68% to as high as 16% in plateletpheresis donors.[8,9]. The incidence of adverse reactions in our study was 6.36% ,that is less compared to the other few studies. All forms of reactions were of mild types and were managed by transfusion physicians only. Out of six donors showing adverse reactions ,five were the first time donors and one was repeat replacement donor. The donors in our study were mainly of the age group from 20 to 40 years and all were male donors. Among 6.36% adverse events in our study, 3.82% was due to donor related and 2.54% was due machine.(table 4)

Table 4:Total adverse events

Reason	Percentage
Donor related	3.82%
Machine related	2.54%
Total	6.36%

The percentage of AEs among healthy donors undergoing plateletpheresis procedures in Dogra et al showed near similar result like our study.(10) Other studies by Philip et al,McLeod et al showed low reaction rate than our study.(11,12) other studies like Bassi et al showed 3.7% adverse reactions.(13) (table 5)The potential donor should meet several requirements to be accepted as a suitable candidate for blood component donation.(14) Criteria such as hematocrit or hemoglobin levels, age, weight, and minimum platelet count are important for the safety of the

donor.(15) In order to prevent citatre toxicity we prophylactically gave oral calcium, in order to prevent vascular injuries staff should be technically sound. All the apheresis donors should be kept for minimum 30 minutes post donation in order to check any adverse reactions. Precautions and close monitoring helps to reduce any forms of reactions.

Overall, platelet usage is likely to increase further, especially because of advances in hematopoietic stem cell transplantation and continued use in solid organ transplants , dengue epidemic, and trauma. Thus, the care of platelet donors is a continuous process, to retain healthy donors and preventing donor reactions.

Table 5: Comparison Between Studies

Study Name	Total AE's
Dogra et al.	5.86%
Bassi et al.	3.7%
Philip et al.	2.72%
McLeod et al.	2.18%
Present study	6.36%

CONCLUSION

Blood donation is a valuable, humane, voluntary contribution, where donors, safety is of paramount importance. An unsatisfied donor is unlikely to return for donation, and such refrainment may eventually reinforce a negative risk perception of blood donations within the community. Careful selection and evaluation of platelet donors by experienced transfusion physicians and presence of experienced nurses or technicians in donation room, who closely attend the donors during and immediately after donation, play an important role in the prevention of adverse reactions in donors. To prevent machine related adverse events, maintenance of machine and proper kit selection is important. Doctors who load the kit should be technically sound. If staff is changed in Apheresis room demonstrations should be given to them about the Apheresis procedures.

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Nil.

Conflicts Of Interest
There are no conflicts of interest.

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