Clinical Indications and Adverse Reactions of Platelet Apheresis

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ABSTRACT

Objective: To determine the clinical indications and adverse reactions of platelet apheresis procedure. **Study Design:** Cross-sectional, observational study.

Place and Duration of Study: Blood Bank of Pakistan Atomic Energy Commission General Hospital, Islamabad, from January 2010 to December 2014.

Methodology: Indications and adverse reaction verified for 200 consecutive platelet apheresis donations performed for 125 patients was included in this study. Data was analysed for descriptive variables using SPSS version 16.

Results: Donor deferral rate in the study was 63.83%. All the donors were males (100%) and replacement donors. Most prevalent blood type was B-positive (n=63, 31.5%), followed by O-positive (n=59, 29.5%). Rh negative groups constituted 13.5% (n=27) of all the donors. Average age of platelet apheresis donors was 28.56 \pm 5.77 years. Maximum numbers of donors were in age range 20 - 30 years. Average weight of the donors was 73.96 \pm 11.96 kg. Mean pre-procedure platelet count of donors was 268,000/µL. The postprocedure average platelet count was approximately 200,000/µL. The mean duration of a platelet apheresis session was 78.27 \pm 26.07 minutes. Average volume of the final product was 412.53 \pm 45.33 ml. Average volume of anti-coagulant acid citrate dextrose used per procedure was 300 \pm 40 ml, 245 ml returned to donor along with returned blood while 55 ml used as anticoagulant in final concentrate. Of total 200, two (1%) final products were contaminated with red cells. Three (1.5%) products were not issued and finally expired. Of the 125 patients for which plateletpheresis procedures were performed, 54 (43.2%) patients were males and 71 (56.8%) were females (M: F=0.76:1). Six donors (3%) had adverse events: three donors (1.5%) had mild reactions, two (1%) moderate reaction, and one donor (0.5%) developing hematoma. None had severe or life-threatening reactions.

Conclusion: Plateletpheresis procedure is relatively safe and forms an important adjuvant to blood bank inventory.

Key Words: Plateletpheresis. Single donor platelets. Blood donors.

INTRODUCTION

In platelet apheresis, commonly known as single donor platelet procedure, blood is drawn from a donor in anticoagulant solution and separated into components. Platelets suspended in plasma are retained as endproduct and the remaining components i.e. red blood cells and plasma are returned to the individual. A single unit of platelet concentrate produced from a unit of whole blood contains, on the average, 7.5×10^{10} platelets and should increase the platelet count by 5 to 10 x 10⁹/L (5,000 - 10,000/µL) in a 70 kg recipient. Apheresis platelet concentrates generally contain 3 - 6 x 10¹¹ platelets, depending on collection practice.¹ Therefore, 6-times more platelets can be collected at one time through the apheresis than through wholeblood donation. Additionally, it has the advantage of reduction in donor exposures and risk of alloimmunization over pools of platelet concentrates made from whole blood collections from several donors. Other potential advantages of single donor platelets over pooled donor platelets are decreased risk of bacterial contamination.

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When patients are alloimmunized to human leucocyte Antigen, single donor platelets are preferred since a hemostatic dose of platelets can be collected from a single HLA-matched, or platelet crossmatch-compatible donor.² This study was carried out as data reported in the medical literature on the prevalence of adverse events in donors is limited and contradictory.

The objective of this study was to determine the clinical indications and adverse reactions of platelet apheresis procedure.

METHODOLOGY

it was an observational study of all the plateletpheresis procedures carried out in retrospect at the blood bank of Pakistan Atomic Energy Commission General Hospital, Islamabad, from January 2010 to December 2014. Every adverse reaction verified during 200 consecutive apheresis donations was recorded. Procedure details and adverse reactions were recorded by the staff on specifically designed proforma. All plateletpheresis procedures were carried out by using closed system apheresis kits C5L on Fresenius Hometech following departmental operating procedures (SOP). Details of plateletpheresis were explained to each donor who gave due consent before the procedure. Donors were selected based on following criteria: weight > 50 kg, age - 18 to 60 years, at least 3 months from last whole blood donation/3 days from last platelet apheresis, hemoglobin

> 12.5 gm/dl, platelet count > 200 x 10^{3} /cmm, absence of any illness, no consumption of non-steroidal antiinflammatory drugs for last 7 days, negative test for HIV, Hepatitis B, Hepatitis C, ABO identical donor for the patient and adequate venous accesses.

After donor selection, according to above criteria, disposable kits were fitted on cell separators and priming was done. As per the manufacturer's recommendations, we used a double venous access with a C5L kit in a dual-needle procedure (program PLT5d DN). The machine parameters were set as per protocol. The following data were entered into the cell separator program for instrument: donor's height, weight, sex, hematocrit (Htc) and pre-apheresis peripheral blood platelet count. Donors were made comfortable on donor bleeding couch. Following collection of platelets, each unit was allowed to rest for at least one hour for optimum disaggregation of platelets before issuance.

All adverse events were recorded by the staff in a specifically designed form. The adverse events occurring during or after the donation were classified as vasovagal reactions, citrate toxicity, physical e.g. haematoma formation or other severe events e.g. cardiopulmonary events. Vasovagal reactions were further divided into mild (pallor, weakness, dizziness, sweating, nausea and/or vomiting, hypotension, lightheadedness, hyperventilation, irregular breathing and bradycardia), moderate (the above symptoms accompanied by transient unconsciousness) or severe (long-lasting loss of consciousness, convulsions, tetany and incontinence) reactions. Citrate toxicity was divided into mild/moderate (paraesthesias, flushed sensation, nausea and/or vomiting) or severe (tetany or seizure and cardiac arrhythmia).

The statistical analysis was carried out using SPSS ver-16. Qualitative variables of this study are gender of blood donors and patients and types of blood groups included in the study. These variables have been expressed as percentage. Quantitative variables include age, weight and platelet counts of blood donor prior and after apheresis procedure. Also duration of platelet apheresis procedure, average volume of final product, anticoagulant used during procedure are quantitative variables. Quantitative variables are expressed as mean ± standard deviation.

RESULTS

A total of 200 plateletpheresis procedures were performed for 125 patients. Total number of donors screened for these procedures was 553, donor deferral rate being 63.83%. Main reason for deferral was blood group of donor being different from recipients. This was followed by platelet count of less than 2,000,00/µL which has been set as lowest threshold of platelet count in our centre for better platelet yield and decreased chances of

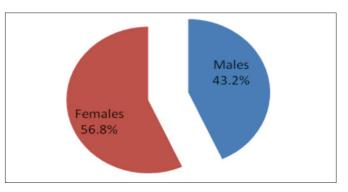


Figure 1: Gender distribution of the patients.

thrombocytopenia in donor. All the donors were males (100%) and replacement donors i.e. friends or relatives of patient, none were voluntary. In all the procedures carried out, prevalent blood type was B-positive (n=63, 31.5%), followed by O-positive (n=59, 29.5%). Rh negative groups constituted 13.5% (n=27) of all the donors. Average age of plateletpheresis donors was 28.56 \pm 5.77 years ranging from 19 to 42 years. Maximum numbers of donors were in age range 20 - 30 years. Average weight of the donors was 73.96 ± 11.96 kg ranging from 55 to 110 kg. Mean platelet counts of donors prior to procedure was 268,000 ± 50,900/µL while postprocedure average platelet count was 200,000 \pm 61,822/µL. The mean duration of a plateletpheresis session was 78.27 ± 26.07 minutes being directly proportional to level of haemoglobin level. Longest plateletpheresis procedure lasted for 3 hours while shortest duration of procedure was of 42 minutes. Average volume of the final product was 412.53 ± 45.33 ml. Average volume of anti-coagulant acid citrate dextrose used per procedure was approximately 300 ± 40 ml, 245 ml returned to donor alongwith returned blood after collection of platelets while 55 ml used as anti-coagulant in final concentrate. Of total 200, two final products (1%) were contaminated with red cells and these were issued after cross-matching with recipient. Three products (1.5%) were not issued and finally expired after 5 days.

Of the 125 patients for which plateletpheresis procedures were performed, 54 (43.2%) patients were males and 71 (56.8%) were females (M:F=0.76:1) as shown in Figure 1. All 125 patients were admitted patients, 106 patients in our own hospital while requests for 19 patients were received from other hospitals.

All the donors were screened for Hepatitis B, C and human immunodeficiency virus type 1 and 2 by enhanced chemiluminescence. Their complete blood counts were performed for haemoglobin levels and platelet counts.

The increase in medical and surgical indications for platelet transfusion, alongwith the new technologies available has resulted in increased use of platelet-

Indication	Number of procedure
Bernard Soulier syndrome. Fracture of Rt. wrist. For surgical Intervention	8
Chronic ITP- for splenectomy	4
Dengue fever in pregnancy	2
Chronic ITP in pregnancy-for elective LSCS	13
Aplastic anemia	4
Undocumented	10
Glanzmann Thrombesthenia with GIT bleeding	6
Dengue fever	47
D.I.C	13
Tropical splenomegaly, hypersplenism	1
Gestational thrombocytopenia- elective caesarean	35
Haematological malignancies	25
Coagulopathy of massive haemorrage	5
Fanconi anemia	9
Acute ITP with bleeding	12
Malaria induced severe thrombocytopenia	1
CLD patients	5

Table II: Adverse events occurring during plateletpheresis donation.

		
Adverse events	Number, n	Percentage
Mild vasovagal reaction	3	1.5
Moderate vasovagal reaction	2	1
Haematoma	1	0.5
Total	6	2

pheresis. Indications and number of procedures carried out in our institute for each of these procedures is depicted in Table I.

A total of 6 donors (%) had some type of adverse event: Three donors (0.5%) had mild reactions, 2 (1%) had a moderate reaction, and one (0.5%) had haematoma. None had severe or life threatening reactions. The adverse reactions are shown in Table II.

Inability to return blood due to technical difficulties occurred in 2 (1%) procedures. No life-threatening adverse effects were reported. Among the donors who suffered adverse events, all were first time platelet donors. The mean volume of the product obtained was 412.53 mL. The mean amount of ACD used during the procedures was 300 mL.

DISCUSSION

The lowest rejection rate (4%) of whole blood donors have been reported in Papua New Guinea. Eight to 15% deferral have been observed in other studies.³⁻⁹

Platelet apheresis is an invasive procedure. Also it requires a greater dedication on the part of the donor because of the prolonged duration of the procedure as compared to whole blood collection. Moreover, for adequate platelet yield, $\geq 3 \times 10^{11}$ / bag and optimal donor safety, the donor selection criteria for platelet-pheresis are more stringent, therefore, optimal donor selection due to greater cost per unit leads to higher rate of donor deferral as compared to whole blood deferrals.

Deferral rate for plateletpheresis procedure in other studies has been documented to be 25.36%, 25.4% and 10.6%. In the present study, the plateletpheresis donor deferral rate was 63.83%. Higher donor deferral rate in our institute is attributable to higher threshold of platelet count (> $200,000/\mu$ L) being employed in our institute.¹⁰⁻¹³

Plateletpheresis donors are ABO identical to recipient. Most frequent blood group in Pakistani population is reported to be B-positive followed by O-positive. This is also reflected in this study as most of recipients and thus donors were Group B Rh positive.¹⁴⁻¹⁹

Average age of plateletpheresis donors in this study was 28.56 years. This is comparable to average age of whole blood donors in Pakistan as reported in other studies. Platelet apheresis donor's average age observed in other studies also showed similar results.^{20,21} Average weight of donors in this study is also comparable to other studies.²²

This study revealed that plateletpheresis for obtaining platelet concentrates can be used in many clinical situations (Table I). Therapeutic plateletpheresis for thrombocytosis due to any cause has not been carried out in our institute.

The plateletpheresis procedure is considered relatively safe. However, several complications may occur. Anticoagulant (ACD) intoxication, which can cause hypocalcemia, may occur. Sign and symptoms of hypocalcemia include perioral numbness, paresthesia of the extremities, tremors, dizziness, chills, and uncoordinated involuntary movements. Vasovagal reaction, which is characterized by pallor, sweating, nausea, hypotension, fainting and loss of consciousness is also a possible complication. Hypovolemia and bruising, which may be related to venipuncture as well as the use of a tourniquet on the arm for a long-time and the continued movement of the hands, is also another possible complication. Adverse events observed in our institute are shown in Table II. Adverse events in a study reported an overall incidence of 1.06% of adverse reactions.²³ Slightly higher incidence of adverse events were observed in our institute. However, no adverse event related to citrate toxicity was observed. This may be due to less volume of ACD being used in our institute which on an average amounts to approximately 300 ml. This volume is about 5% less than those employed by other institutes.22

Of 1.06% adverse events reported by 0.68% were vasovagal in nature while rest of 0.38% were of citrate toxicity.²³ None of them were very severe adverse events. Similarly, in this study, vasovagal adverse events were most frequent and no severe/life threatening adverse events were observed. In another study, pain or haematoma at a venipuncture site was the most commonly observed (1.15%) of donations followed by vasovagal nausea and/or vomiting, (0.87% and 0.13%).

Haematoma formation in this study was observed in one case only at initial stages when plateletpheresis procedure was being established in our institute. Use of dialysis needle was initiated as 18G cannula failed to provide inlet pressure necessary for procedure resulting in undue prolongation of plateletpheresis. This reduction was due to familiarization of blood bank staff with use of dialysis needle.²⁴

Platelet concentrates have the shortest expiry time of all routine blood components. These are stored at room temperature and thus there is associated risk of bacterial growth at this temperature, particularly beyond the shelf-life of 5-day. Wastage of random donor platelet concentrates has, therefore, been documented to be as high as 20.8%.²⁵ However, almost 100% single donor platelet concentrates get utilized. Similarly, in our institute, 98.5% of prepared single donor platelets were utilized.

CONCLUSION

Platelet apheresis procedure is a relatively safe and forms an important adjuvant to blood bank inventory. It is also useful in wide variety of clinical situations.

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