Original Article

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Pathology Section

A Retrospective Analysis of Apheresis Donor Deferral and Adverse Reactions at a Tertiary Care Centre in India

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ABSTRACT

Introduction: With increasing demand of platelet component each day, blood bank plays a pivotal role in ensuring supply of safe blood as and when required. Plateletpheresis procedure is a relatively simple, safe and important adjunct to blood bank inventory. However, recruitment of healthy blood donors is a challenge that the health industry is facing today.

Aim: To determine the reasons and rates of apheresis donor deferral along with investigation of adverse reactions encountered during the procedure.

Materials and Methods: Records of single donor apheresis were retrospectively analysed from 1st January 2010 to 31st December 2014. The study was carried out at Blood Bank, Safdarjung Hospital, New Delhi, India. The donor details that were studied included – age, sex, type of donation (voluntary/ replacement/ repeat), reason for donor deferral and type of adverse reaction, if encountered during the procedure.

Results: Among the 478 donors screened for plateletpheresis procedure during a study period of 5 years, 134 (28.03%) were deferred. Temporary deferrals accounted for majority (93.28%) of the deferrals. Low platelet count (50.75%) was the main reason of donor deferral followed by low haemoglobin (20.89%). Amongst the 344 selected donors, 15 (4.36%) had some type of adverse reaction associated with the procedure.

Conclusion: We suggest that the selection criteria for plateletpheresis donors should be revised to deal with shortage of apheresis donors. The criteria regarding minimum pre-procedure platelet count (above1.5 lac/µl) and haemoglobin (above 12.5 g/dl) need to be lowered so as to suit the Indian scenario. The lower adverse reaction rates, 14/344 (4.06%) associated with this procedure encourages safety of donors and is important in recruitment of new donors.

Keywords: Adverse event, Deferral, Plateletpheresis, Selection criteria

INTRODUCTION

Today effective transfusion therapy depends on the availability of different blood components. Component transfusion therapy allows optimal use of blood, which is a limited natural resource.

Platelet concentrates, prepared from whole blood are generally referred to as random donor platelets to distinguish them from single donor platelets produced by apheresis. The process of selectively removing platelets from the blood is termed as plateletpheresis or thrombocytapheresis. Routinely the number of platelets in an apheresis product is equivalent to 6-10 random platelet concentrates and contains at least $3.0x10^{11}$ platelets [1].

Platelet transfusions have been shown to prevent major haemorrhage and improve survival in thrombocytopenic patients [2]. The number of transfused platelet components is growing owing to the increasing number of patients treated for haematological malignancies, functional platelet disorders and disorders causing decreased platelet production. Dengue epidemics in the country have also contributed to increased demand during last 10-15 years [3].

Platelet prepared by apheresis procedures provide adequate dose from a single donor and as such patient is exposed to less number of donors, thus reducing risk of transfusion transmitted infections, bacterial contamination and alloimmunization due to reduced donor exposure [4,5]. In addition, it also prevents chances of refractoriness to a great extent [1].

Compared to whole blood donation, apheresis has some advantages for the donor, including a lesser loss of red blood cells, which means that even women with low haemoglobin values could undergo apheresis. However, apheresis can also lead to specific adverse events such as citrate toxicity or, for single needle devices, extracorporeal circulation reactions [6-8]. Rate of complications varies from 0.89 to 4.8% [9,10]. However, as compared to whole blood donation, it is more costly and requires more dedication on part of donor, because of the prolonged duration of the procedure [11].

Blood bank plays pivotal role in ensuring supply of safe blood as and when required. Recruitment of healthy blood donors is a challenge that the health industry is facing today. Data reported in the medical literature on the prevalence of adverse events in apheresis donors and studies on apheresis donor deferral are limited. Determination of reasons and rates of donor deferral along with evaluation of adverse reaction encountered during the procedure can help in planning more efficient recruitment strategies and donor selection criteria. Thus, this study aimed to define the reasons and rates of apheresis donor deferral alongside examination of adverse reactions met during the procedure, which can help in planning more competent recruitment strategies and donor selection criteria.

MATERIALS AND METHODS

This retrospective study was carried out from 1st January 2010 to 31st December 2014. Data was collected from the records maintained by blood bank, Safdarjung Hospital, New Delhi, India. A total of 478 donors were screened for plateletpheresis procedure during the period of 5 years.

As per the standards of Drug and Cosmetic act, Government of India; informed written consent were taken for above study in

form of explanation of procedure to the apheresis donors, post donation advice, adverse reactions and mandatory testing and if seroreactive, referral to Integrated Counseling and Testing Centers (ICTC), and counselling.

A detailed history was taken from the donors and they were selected as per the following criteria for Single Donor Platelet (SDP) preparation in accordance with the hospital protocols:

1. Weight > 55 kg
2. Age - 18 to 65 years
3. At least three months from last donation/three days from last plateletpheresis
4. Haemoglobin >12.5 gm/dl
5. Platelet count > 150 × 10^3/µl
6. Absence of any illness
7. No consumption of non-steroidal anti-inflammatory drugs for last seven days
8. Negative test for HIV, Hepatitis B, Hepatitis C, Syphilis and Malaria.
9. ABO identical donor for the patient
10. Adequate venous access.

The blood samples of donors were collected for complete blood count as well as for Transfusion Transmitted Infection (TTI) testing. Complete haemogram was measured on Beckman Coulter. The samples were tested for HIV, HBsAg, HCV using 4th generation enzyme immunosorbent assay (ELISA; Biorad), Treponema Pallidum Haemagglutination assay (TPHA; Biorad) for Syphilis and Rapid Malaria Antigen test for malaria.

Donors fulfilling the criteria were recalled as per patients's requirements and apheresis procedure was carried out TrimaAccel® Automated Blood Collection System.

Adverse events requiring any intervention or treatment (e.g., citrate toxicity, vasovagal reaction, haematoma) were documented by a staff using a standardised format provided by the department.

The classification of adverse events was based on the clinical manifestations presented by the donor [12]. The following criteria were used:

1. Mild clinical complications– Syncope, malaise, dizziness, sweating, paresthesia, headache and paleness.

2. Moderate medical complications– Nausea, vomiting, hypotension and arrhythmia.

3. Severe medical complications– Hyperventilation, tetany, apnea, loss of consciousness, convulsive crisis and haematoma.

RESULTS

In the present study, among the 478 donors screened for plateletpheresis procedure during the study period of 5 years, the plateletpheresis donor deferral rate was 28.03% (134/478). A total 344 plateletpheresis procedures were carried out during this period. The deferral rate was significantly higher in males (96.27%) belonging to age group 25-35 age group. The demographic profile of deferred donors is tabulated in [Table/Fig-1].

The reasons for deferral were divided into temporary and permanent causes. Temporary deferrals (93.28%) accounted for majority of the deferrals. Among them, low platelet count (50.75%) emerged as the main reason which was followed by low haemoglobin (20.89%) and low weight (6.72%). Other causes are tabulated in [Table/Fig-2].

Of the 68 donors deferred due to low platelet count, 16 (23.52%) had counts in the range of 1.3-1.49 lac/µl. Twenty eight donors were deferred for anaemia, of which 11 (28.94%) had haemoglobin in the range of 11.5- 12.4gm%.

AGE RANGE (years)	N = 134	%
18-24	41	30.60
25-34	69	51.49
35-39	17	12.69
≥ 40	7	5.22
GENDER	**N=134**	**%**
Male	129	96.27
Female	5	3.73
TYPE OF DONATION	**N=134**	**%**
Voluntary	35	26.12
Replacement	91	67.91
Repeat donors	8	5.97

[Table/Fig-1]: Demographic characteristics of donors.

TYPE OF DEFERRAL	N=134	%
Temporary	125	93.28
Permanent	9	6.72
TEMPORARY DEFERRALS		
Low platelet count	68	50.75
Anaemia/Low haemoglobin	28	20.89
Underweight	9	6.72
Poor venous access	7	5.22
High blood pressure	4	2.98
History of recent vaccination	3	2.24
On NSAIDs	3	2.24
On antibiotics	2	1.49
Skin allergy	1	0.75
PERMANENT DEFERRALS		
HEPATITIS B positive	5	3.73
HEPATITIS C positive	3	2.24
SYPHILIS positive	1	0.75

[Table/Fig-2]: Causes of plateletpheresis donor deferral.

ADVERSE REACTIONS	N	%
Mild	8	2.33
Moderate	2	0.58
Severe	4	1.16
Mild & Severe Reaction	1	0.29
TOTAL	15	4.36

[Table/Fig-3]: Adverse reactions during plateletpheresis procedure (One donor had both mild and severe reaction in the form of syncope and haematoma).

Amongst the 134 donor deferred, 5 of them had dual causes of deferral, 3 had low platelet count along with low haemoglobin, one had low platelet count along with low weight and one had low haemoglobin along with low weight.

During the study period we evaluated the 23 apheresis donors with platelet counts in the range of 1.5-1.8 lac/µl, who underwent plateletpheresis procedure. Although the platelet yield was lower than the recommended (range 2.1-3.0x10^{11}/bag), 2 of them developed adverse reaction in the form of vasovagal syncope and haematoma formation.

As shown in [Table/Fig-3], amongst the selected 344 donors, a total of 15 (4.36%) donors had some type of adverse event: 8 (2.33%) had mild reactions, 2 (0.58%) had a moderate reaction, 4 (1.16%) had haematomas (severe reaction), and 1 (0.29%) had a mild reaction associated with haematoma. Among the donors who suffered adverse events, 13 (3.48%) were first time platelet donors and 2 (0.58%) were repeat donors.

DISCUSSION

Plateletpheresis donor deferral rate in our study was 28.03%, which is comparable to 25.4% in a study by Tondon et al., and Pujani et

al., who reported a rate of 27.5% [11,13]. On the contrary, Pandey et al., observed a lower deferral rate of 10.6% [14].

Majority of the donors in our study were young (<35years). Voluntary donations accounted for 26.12% and repeat donors accounted for 5.97%. We believe that it is imperative to equip the potential donors with proper knowledge of the procedure and the deferral criteria so that those with temporary deferrals can return at a later date. Constant counselling of patient's relatives and friends and motivation of the staff can help us achieve the goal. Non-monetary incentives like pre-donation medical check-ups and testing could nurture the habit of regular blood donors.

Among temporary deferrals (93.28%) low platelet count (50.75%) emerged as the main reason which was followed by low haemoglobin (20.89%) and low weight (6.72%). These findings are concurrent with other studies in literature by Tondon et al., Pujani et al., and Pandey et al., [11,13,14] .

Twenty eight donors were deferred for anaemia, of which 11 (28.94%) had haemoglobin in the range of (11.5- 12.4%). Studies by Tondon et al., Fraser et al., suggest lowering the cut-off value for plateletpheresis from 12.5 g/dL to 11.5 g/dL has no deleterious effect on donor safety as the blood loss is minimal [11,15]. Thus, lowering the cut off criteria can allow more participation and reduce the deferral rates.

During the study period we evaluated the 23 apheresis donors with platelet counts in the range of 1.5-1.8 lac/µl. Despite lower platelet yield (range 2.1-3.0 $x10^{11}$/ bag), only two of these donors developed adverse reaction. Rogers et al., also demonstrated that plateletpheresis procedure is safe in donors with low platelet counts (150–180 x 10^9/L) even after extending the collection time to 120–140 min while maintaining the adequacy of yield [16].

A 4.06% of the donors had some type of adverse event. This low incidence is concurrent with other studies in literature and indicates that plateletpheresis procedure is well tolerated by donors [17]. However, some studies also suggest higher incidence of plateletpheresis as compared to plasmapheresis and leukapheresis [18-20].

LIMITATION

The main limitation of this study is paucity of available literature regarding plateletpheresis donor deferral and selection criteria.

CONCLUSION

As a part of a tertiary care centre, where numerous SDP requisitions have to be dealt daily with shortage of apheresis donors; we want to take into account findings of the present study. We suggest that the selection criteria for plateletpheresis donors should be revised. The criteria regarding minimum pre-procedure platelet count (above1.5 lac/µl) and haemoglobin (above 12.5 g/dl) need to be lowered so as to suit the Indian scenario. Since temporary deferrals and low platelet count account for majority of the deferral, a repeat platelet count should be performed on donors with lower platelet counts and should be followed up so as to reduce the deferral rates.

Further, the results of our 5-year analysis states apheresis and blood donation are safe procedures for the donor with a low incidence of adverse reactions; the adverse reactions that did occur were mostly mild and resolved rapidly. The lower adverse reaction rates associated with this procedure encourages safety of donors and is important in recruitment of new donors.

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