Original Research Article

Retrospective analysis of donor deferral for plateletpheresis at a regional transfusion center, in North-West India

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ABSTRACT

Background: Single donor platelet (SDP) is one of the valuable component for thrombocytopenic patients for obtaining good post transfusion count increment, good yield of product is required. Proper donor selection has a crucial role in in safety and quality of product therefore proper screening of donor is mandatory. The aim was to find out reasons and frequency of plateletpheresis donor deferral and to encourage safety of donor for recruitment of new SDP donors.

Methods: A retrospective analysis of data was done over a period of 1 year from June 2018 to May 2019 from the data centre of the institute.

Results: Out of 1365 donors, 1200 were selected for plateletpheresis procedure and remaining 165 donors were deferred for various reasons. The predominant age of donors ranges from 25-35 years. Among the deferred donors temporary donors accounted for 93.33% and permanently deferred donors were 6.61. Most common cause for deferral were poor venous access 52 (31.51%), Low platelet counts 32 (19.39), low Hb 26 (15.75%), underweight 24 (14.54%), under medication 9 (5.45%), alcohol intake within 24 hours 6 (3.63%) and others like tattoos, infections/inflammations at phlebotomy sites 5 (3.03%) and most common reason for permanent deferral were sero-positivity for HbsAg 6 (3.63%), chronic diseases 4 (2.42%) (cardiovascular diseases bronchial asthma), others 1 (0.6%).

Conclusions: For obtaining good yield of product, proper donor screening is required. Temporary deferred donors should be counselled properly and encouraged for further donation when comes under selection criteria. Donor selection criteria for apheresis may be revised.

Keywords: Plateletpheresis, Selection criteria, SDP, Deferral, Thrombocytopenia

INTRODUCTION

Platelet transfusions have been found to prevent major haemorrhage and improve survival in patients with thrombocytopenia.¹

There are huge number of advantages of SDP transfusion over random donor platelets concentrates (RDP) which include better increment of platelet counts, reduced risk of transfusion transmitted diseases, less chances of allo-immunization due to less donor exposure, bacterial contamination. The demand of SDP is increasing over time because of its merits over RDP. As per AABB guidelines, plateletpheresis (SDP) unit should have platelet count of at least 3×10¹¹ which in turn increases platelet count by 30,000-60,000 per cubic mm in a non-bleeding patient.¹¹ One unit of SDP is equivalent to 4-6 units of random platelet concentrates.²
The epidemics of dengue fever, advancements in blood transfusion services, donor education and motivations has been major reasons for the increasing awareness regarding platelethpheresis in our country.\textsuperscript{3} Platelethpheresis required stringent donor selection criteria for adequate platelet yield and for optimal patient and donor safety.\textsuperscript{4} Specific techniques and investigations and prolonged duration of procedures required so higher donor dedication is required than whole blood donation. Stringent donor selection criteria and higher cost per procedure leads to higher donor deferral rate as well as greater donor depreciation.

There is inadequacy of literature concerning donor deferral characteristics in platelethpheresis.\textsuperscript{5,6} Current study was aimed to analyse causes of donor deferral and parameters affecting platelet yield that can help to expend already existed platelethpheresis donor pool as well as to determine if certain criteria can be reviewed. Therefore, a retrospective analysis was done for study of causes, their frequency and type of platelethpheresis donor deferral at tertiary level health care centre.

\textbf{METHODS}

The retrospective analysis of data was done over a period of 1 year from June 2018 to May 2019 from the data center of department of immunohaematology and transfusion medicine of study center.

The following characteristics were noted on each SDP donor like age, sex, weight, complete haemogram (hemoglobin, red cell indices, platelet count), cause of deferral (temporary/permanent). The donor selection criteria for platelethpheresis were followed at our center included as follows.

\textbf{Inclusion criteria}

Patients aged 18-60 years, weight >55 kgs, hemoglobin $\geq$12.5 gm/dl, pre platelet count must be 1.5-4.5 lac/cumm were included in the study. There must be adequate venous access to get uninterrupted blood flow. Donation interval for apheresis, should be at least 48 hours after platelet/plasma (apheresis shall be kept not more than twice a week, limited to maximum 24 in one year). After whole blood donation a platelethpheresis donors was not accepted before 28 days. Apheresis donor was not accepted for whole blood donation before 28 days from the last platelethpheresis, if reinfusion of red cell was not complete then the donors were not accepted within 90 days. Serology negative for TTI (HIV 1 and 2, HBsAg, HCV, syphilis and malaria). Patients with no intake of NSAIDs drugs in the last 72 hours and donor should be ABO identical for the patient.

In addition, donor eligibility criteria for whole blood donation was followed in accordance with the drugs and cosmetics act 1940 and rules 1945 therein.

\textbf{Exclusion criteria}

Donors who did not match platelethpheresis donation criteria as per drug and cosmetic act were excluded from study.

Thus, after donor counselling thorough history was taken and clinical examination was done on each SDP donor and samples were collected for complete blood count as well as for transfusion transmitted diseases testing. The samples were tested for HIV 1 and 2, HBsAg, HCV ELISA technology, rapid card test for syphilis and rapid malaria antigen card test for malaria parasite. The donors who fulfilled all the above criteria were selected and the apheresis procedure was performed using haemonetics MCS+, based on intermittent flow cell separation, Amicus and Comtac machine from Fresenius based on continuous cell separation method.

\textbf{Statistical analysis}

SPSS software version 20 was used was statistical analysis.

\textbf{RESULTS}

Total 1365 SDP donors were screened during the period of study, out of them 1200 donors were selected for donation and 165 (12.08\%) were deferred for various reasons. The predominant age of donors ranges from 25-35 years. Among the deferred donors, temporary donors accounted for 93.33\% and permanently deferred donors were 6.61\%. Most common cause for deferral were poor venous access 52 (31.51\%). Low platelet counts 32 (19.39\%), low Hb 26 (15.75\%), underweight 24 (14.54\%), under medication 9 (5.45\%), alcohol intake within 24 hours 6 (3.63\%) and others like tattoos, infections/inflammations at phlebotomy sites 5 (3.03\%) and most common reason for permanent deferral were seropositivity for HbsAg 6 (3.63\%), chronic diseases 4 (2.42\%) (cardiovascular diseases bronchial asthma) others 1 (0.6\%).

\textbf{Table 1: Demographic details of donors.}

| Demographics | N=165 | % |
|--------------|-------|---|
| **Age range (in years)** |     |    |
| 18-24        | 35    | 21.2 |
| 25-35        | 73    | 44.2 |
| 36-45        | 46    | 27.8 |
| >45          | 11    | 6.7 |
| **Gender**   |     |    |
| Male         | 161   | 97.5 |
| Female       | 04    | 2.5  |
| **Type of donor** |     |    |
| Voluntary    | 47    | 28.4 |
| Replacement  | 118   | 71.6 |
Table 2: Causes of donor deferral for plateletpheresis.

| Deferral          | Cause of deferral                        | Total no | %     |
|-------------------|------------------------------------------|----------|-------|
| Temporary deferral (93.3%) | Poor venous access                        | 52       | 31.51 |
|                   | Low platelets counts                      | 32       | 19.3  |
|                   | Low Hb                                    | 26       | 15.7  |
|                   | Under weight                              | 24       | 14.5  |
|                   | Under medication                          | 9        | 5.4   |
|                   | Alcohol intake                            | 6        | 3.6   |
|                   | Others (tattoo, infection, inflammation)  | 5        | 3.03  |
| Permanent deferral (6.6%) | Sero-reactive                             | 6        | 3.6   |
|                   | Chronic disease (cardiovascular diseases, bronchial asthma) | 4 | 2.4 |
|                   | Others                                    | 1        | 0.6   |

Figure 1: Causes of donor deferral for plateletpheresis.

DISCUSSION

Platelet transfusion is an important therapeutic modality which is imparted to reduce morbidity and mortality in patients with severe thrombocytopenia who are at very high risk of spontaneous bleeding. Patients with haematological malignancies, undergoing chemotherapy for leukaemia, dengue haemorrhagic syndrome, aplastic anaemia, idiopathic thrombocytopenic purpura, septic shock, bone marrow transplantation. In these patients SDP was superior component to RDP with less chances of alloimmunization, transfusion transmitted infections, better yield, as it was a controlled process where the equipment extracts platelets according to the donor height, weight, haematocrit, platelet count and blood volume. However, risk of adverse events were always associated to some extent.

The most significant problem for use of apheresis platelets was availability of less number of SDP donors and it was due to lack of donor education, motivation, more procedure time than whole blood donation, uncooperation by donors and partly due to lack of safety awareness. Besides these proper venous access was essential for maintaining proper draw and return by machine during entire procedure. Ineligibility of apheresis donors due to low platelet count, low haemoglobin, underweight or underlying medical conditions further aggravated the problem for selection of plateletpheresis donor.

In the current study, the donor deferral rate for plateletpheresis was 12.08%, which was similar to Pandey et al who observed a deferral rate of 10.6%.6
Tondon et al reported a deferral rate of 27.5% which was quite higher than present study.\(^5\)

In present study, most of the donors were deferred for temporary reasons. Thus, the most common deferral reason in our study was inappropriate vascular access in 31.51% of the donors which was comparable with Dogu et al.\(^7\) Whereas in other studies like Pujani et al and Dua et al the most common reason for donor deferral was low platelet counts.\(^3,8\)

To use continuous flow systems for platelethpheresis, suitable vascular access should be available. Second most common reason for donor deferral was low platelet counts. Although DGHS guidelines regarding SDP donor state that a platelet count was not required prior to the first procedure for an apheresis donor.\(^9\) However, the yield of apheresis platelets also depended on the pre procedure platelet counts, due to these reasons our policy was to select a donor of platelet count minimum 1.5 lacs/cumm and preferably in the range of at least 1.5-2 lacs/cumm so the donor’s health did not compromise. Pre procedure platelet count effects platelet yield. The minimum platelet yield which was required for final volume was at least 3×10\(^11\) (ranges 3.5-5.5×10\(^11\)) and to get this yield minimum platelet count in donor should be 1.5-4 lacs/cu mm of blood.\(^11\) Rogers et al exhibited that platelethpheresis procedure was safe even after extending the procedure time to 120-140 minutes while maintaining the appropriate platelet yield in donors with low platelet counts (150-180×10\(^9\)/l).\(^10\) As per AABB there was around 25% of platelet loss in donor after each platelethpheresis procedure.\(^11\)

In another study done previously in the same department the anemia (low Hb) was the major reason (35.9%) for deferral of whole blood donors whereas in apheresis donors it was only 15.7% in present study. Another major cause for donor deferral include underweight (14%) and drug intake (5.4%), which was comparable with Arora et al.\(^12\)

Most common drug consumed before donation was non steroid anti-inflammatory drugs (NSAIDs) donors were asked/educate not to consume any NSAIDs before SDP donation for next donation.

Most common cause for permanent deferral was detection of TTI in the donors, those donors were counseled and referred to respective facilities according to guidelines and educate donors for self-deferral for next time.

In rare/emergency circumstances if ABO identical donor was not available, non-group specific SDPs can be transfused to patients, this could narrow down the apheresis donor deferrals to some extent.

**Limitations**

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

**CONCLUSION**

SDP is an important blood component because of its preparation method and short shelf-life, thus selection of the donors for apheresis should be performed very cautiously so as not to harm the donor and supply the demand of the recipient appropriately. In developing country like India blood transfusion services are dependent on voluntary donors rather than replacement donors that is why there is always shortage of apheresis donors. Considering all these factors and the findings of the current study, we would like to recommend that the eligibility criteria for plateletpheresis donors should be revised and relaxed in reference to Hemoglobin and total pre platelet counts. By improving technical skills in phlebotomy procedure for apheresis, use of continuous flow cell separator and finally increasing social awareness may decrease the deferral rates.

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**Ethical approval:** The study was approved by the Institutional Ethics Committee

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