



# Plateletpheresis donor deferral pattern: A retrospective 4-year data analysis at tertiary care center in India

Brijesh Kumar Yadav, Harsha Shrivastava, Rahul Katharia, Rajendra K. Chaudhary

## Abstract:

**BACKGROUND:** Increasing demand of single donor platelet requires blood banks to expand the donor pool. A reassessment of donor deferral criteria for plateletpheresis is required to ensure that this increasing demand is met without compromising on product quality and donor safety.

**AIMS:** (1) To list the various causes of SDP donor deferral. (2) To discuss various approaches to minimize it.

**MATERIALS AND METHODS:** Data of plateletpheresis donor deferral were collected from records retrospectively over a period of 4 years from January 2017 to December 2020.

**STATISTICAL ANALYSIS:** All statistical tests were performed using IBM SPSS software for Windows version 20. Categorical variables were presented as proportions, while continuous variables were presented as mean with standard deviation, mean calculated  $P < 0.05$  was considered statistically significant.

**RESULTS:** Out of the 7478 donors screened for plateletpheresis procedure, 3232 (43.2%) were deferred among which 3089 (42.5%) were male and 142 (63.1%) were female donors. Majority (96.5%) of deferral were temporary. These included low platelet count (47.4%) followed by poor venous access (22.4%) and low hemoglobin (Hb) (7.2%). Among the donors deferred for low Hb, 24.7% (58 out of 234) had Hb between 12 and 12.4 g%. Similarly, among donor deferred for low platelet count, 12% (184 out of 1532) had platelet count between 140 and  $149 \times 10^3/\mu\text{l}$ .

**CONCLUSION:** There is potential for increasing the number of eligible plateletpheresis donors if the present donor selection criteria were relaxed to a minimum Hb of 12 g/dl and minimum platelet count of  $140 \times 10^3/\mu\text{l}$ .

## Keywords:

Donor deferral, low hemoglobin, low platelet, plateletpheresis, selection criteria

## Introduction

SDP has numerous benefits over RDP including better yield thereby allowing longer interval between platelet transfusions and decreased risk of transfusion-transmitted diseases, alloimmunization,<sup>[1]</sup> and febrile nonhemolytic reaction.<sup>[2]</sup> This has led to increased demand of SDP resulting in a critical need for enrolment of additional plateletpheresis donors at many institutions.

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Recruitment of plateletpheresis donors, however, is challenging since the selection criteria include all those that are applicable for whole blood donation plus various other parameters. While this ensures adequate platelet yield and optimal donor and patient safety, it also leads to higher donor deferral and donor attrition.

## Aims

1. To list the various causes of SDP donor deferral
2. To discuss various approaches to minimize it.

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Department of Transfusion  
Medicine, Sanjay Gandhi  
Postgraduate Institute  
of Medical Sciences,  
Lucknow, Uttar Pradesh,  
India

## Address for correspondence:

Dr. Rahul Katharia,  
Department of Transfusion  
Medicine, Sanjay Gandhi  
Postgraduate Institute  
of Medical Sciences,  
Lucknow - 226 014,  
Uttar Pradesh, India.  
E-mail: rk.kats@gmail.com

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## Methods

This retrospective study was conducted at the Department of Transfusion Medicine in a tertiary care hospital in Northern India. Plateletpheresis donor deferral data were collected for 4 years (January 2017–December 2020).

For screening of plateletpheresis donors, a standard operating procedure for donor selection is followed at our center. As per the protocol, donor blood samples are obtained before the actual procedure for required hematological and infectious disease testing. First and foremost, ABO grouping of donors is performed. Donors having ABO group identical to that of the patient is preferred. In special circumstances, non-ABO identical donors can also be selected. Donors are then asked to fill a plateletpheresis screening form and their suitability for platelet donation is determined by taking a detailed medical history in accordance with the Drug and Cosmetic Act of India and performing a physical examination for assessing the venous access. When found suitable, 10 ml venous blood sample is collected from the donor. A complete blood count is performed on electronic cell counter (Medonic M-series, Sweden) using EDTA sample. If counts are within normal range (hemoglobin [Hb] >12.5 g/dL, hematocrit >38%, white blood cell (WBC) count:  $4-11 \times 10^3/L$ , platelet count  $>150 \times 10^9/L$ ), the samples are screened for transfusion transmitted infections including HIV, HBV, and HCV by chemiluminescence (Ortho Clinical Diagnostics, USA) and Nucleic Acid Amplification Testing (Roche Diagnostics, Germany). Donors are screened for Syphilis by RPR card test (Carbogen, Tulip Diagnostics) and malaria by a rapid test for (Parabank, Tulip Diagnostics). If nonreactive, donor is considered eligible for platelet donation. Actual plateletpheresis procedure is done when clinician sends requisition for SDP. Plateletpheresis procedure is done on Trima Accel (COBE-Trima 1998, Lakewood, USA), Amicus™ Separator, software version 2.52 (Fenwal, Lake Zurich, IL, USA) and COM.TEC, software version 4.0 (Fresenius HemoCare GmbH, Bad Homburg, Germany).

### Statistical analysis

All statistical tests were performed using IBM SPSS software for Windows version 20 (IBM Corp, Armonk, NY, USA). Categorical variables were presented as proportions, while continuous variables were presented as mean with standard deviation (SD), mean calculated  $P < 0.05$  was considered statistically significant.

## Results

During the study, 7478 individuals (7253 males and 225 females) were registered as potential plateletpheresis donors of which 3232 (43.2%) were deferred due to

various reasons. Out of total of 7253 male donors registered, 3089 (42.6%) were deferred while 63.1% (142 out of 225) of female donors were deferred [Figure 1].

Temporary deferrals accounted for 96.5% of all the deferrals [Table 1].

For male donors, low platelet counts ( $<150 \times 10^9/L$ ) while for female donors, poor venous access was the most common cause for deferral. Total donor deferral due to poor vein was 22.4%. Due to low platelet and low Hb, total donor deferrals were 49.2% and 7.2%, respectively [Table 2].

However, only 6.4% male donors were deferred due to low Hb in contrast to 30.3% deferral rate among the female donors [Table 1]. Of the total 137 female deferred, 5 (3.5%) were deferred permanently, 3 for being multiparous, 1 each for history of asthma and RPR reactive.

## Discussion

Recent years have witnessed an increased demand of SDP. This increasing demand has stressed on the need of eligible platelet donors from whom quality product of optimal yield can be collected so that maximum rise in platelet count of recipient can be achieved. In the present study, plateletpheresis donor deferral rate was 43.2%. This is much higher than that observed by Tondon *et al.*<sup>[3]</sup> (27.5%) and Pujani *et al.*<sup>[1]</sup> (25.36%). Majority of the deferrals were temporary. Imparting potential donors with proper knowledge of the deferral criteria can make them return at a later date. Among temporary deferral, low platelet count (49.1%) appeared as the main reason. This finding is concurrent with studies in by Tondon *et al.*<sup>[3]</sup> Pujani *et al.*<sup>[1]</sup> and Arora *et al.*<sup>[4]</sup> Low platelet count in normal donor population is a concern and affects the availability of suitable apheresis donors for apheresis. We could not find any reason for low platelet count in apparently healthy donors. Das *et al.* observed low platelet count among the blood donor population in Eastern India and commented on poor platelet yield in random donor platelets.<sup>[5]</sup> High donor deferral (22.4%) due to poor vein was due to the fact that the majority of our procedures were done on double needle apheresis device.

Deferral of potential whole blood donors with Hb level  $<12.5$  g/dL is reasonable as PRBCs prepared from the whole blood of such donors will be of suboptimal quality and there will also be an adverse effect on donor's health. However, a similar Hb cutoff in potential plateletpheresis donor is less justified. Unlike whole blood donation, in plateletpheresis donor's blood is separated into components, platelets are selectively

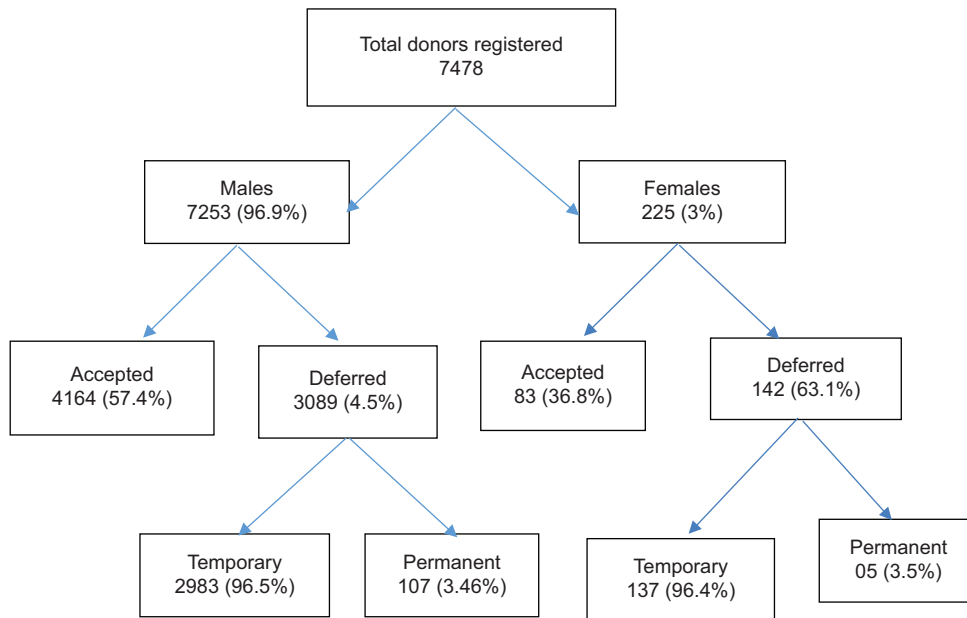


Figure 1: Deferral rates of apheresis blood donors

Table 1: Causes of temporary deferral of male and female donor

Causes, n (%)	Male, n (2983/3089; 96.5%), n (%)	Female, n (137/142; 96.4%), n (%)	P
Medical history/examination			
Poor vein access	667 (22.4)	57 (41.6)	0.000
Infection at site/fungal infection	58 (1.9)	1 (0.7)	
On medication	36 (1.2)	-	
Abscess/open wound	19 (0.6)	-	
Dog bite/rabies vaccination	11 (0.4)	-	
Tattooing	7 (0.3)	-	
Laboratory investigation			
Low platelets count	1509 (50.6)	23 (16.7)	<0.01
Low haemoglobin	191 (6.4)	43 (30.5)	0.05
Major ABO incompatible	175 (5.8)	2 (1.5)	
High total leukocyte count	145 (4.9)	3 (2.2)	
High blood pressure	31 (1)	1 (0.7)	
High haemoglobin	14 (0.5)	-	
Physiological			
Underweight	43 (1.4)	7 (5.1)	
Recent donation	16 (0.5)	-	
Underage	10 (0.3)	-	
Overage	2 (0.06)	-	
False deferral			
Unwilling	20 (0.7)	-	
Absent on call	8 (0.3)	-	
Miscellaneous*	24 (0.8)		

\*Tuberculosis, cold and cough, history of seizure/dengue/malaria/typhoid/jaundice/septoplasty/previous Grade 3 reaction/anxiety/sample clotted/reaction during sampling/needle injury/history of leprosy/eye infection

Table 2: Increment in apheresis donors with relaxed criteria

Criteria	Existing values	Deferred donors, n (%)	Relaxed criteria	Deferred donors, n (%)	Increment in eligible donors, n (%)
Preprocedure hemoglobin (g/dl)	≥ 12.5	234 (7.2)	12-12.4	176 (5.4)	58 (1.3)
Preprocedure platelet count (×10 <sup>3</sup> μ/dl)	≥ 150	1532 (49.2)	140-149	1348 (43.2)	184 (4)

collected while the rest of the components, i.e., red cells and plasma are returned back to the donor. Red cells loss in plateletpheresis is minimal and mainly in the form of whole blood left in the tubing of the plateletpheresis kit at the end of the procedure which is around 20–30 ml. Even in occasional cases of failure to perform reinfusion, the blood volume lost will not lower the Hb of the donor by more than 0.5 g/dl.<sup>[3]</sup>

Females tend to have lower baseline Hb than males. Thus having a higher cutoff for Hb causes disproportionate exclusion of female plateletpheresis donors. Even in our study, 26.1% female donors were deferred due to low Hb while only 6.4%. Male donors were deferred due to low Hb. Fraser *et al.*<sup>[6]</sup> in their study observed that lowering the cutoff for Hb from 12.5 to 11.5 g/dL had no deleterious effect on donor's health. They recommended that the lower Hb cutoff of 11.5 g/dL is a safe and relevant threshold for accepting female plateletpheresis donors and would allow more participation by women in blood donor programs. According to the study by Tondon *et al.*<sup>[3]</sup> donors with lower Hb values but normal mean corpuscular volume (MCV) and red blood distribution width (RDW) can be safely selected as potential donors. Mendez *et al.*<sup>[7]</sup> in their study found that SDP donation by donors with Hb concentration <12.5 g/dL can be carried out safely and efficiently.

In our study, 7.2% of the donors deferred for low Hb had Hb values in the range of 12–12.4 g/dl, however, their platelet count was  $>150 \times 10^9/L$ . If Hb cutoff is relaxed, then these donors can also be included in the donor pool provided their MCV and RDW values are normal. This will decrease the donor deferral due to low Hb from 7.2% to 5.4% thereby expanding the donor pool [Table 2].

47.4% of donors in our study were deferred for having platelet count  $<150 \times 10^9/L$ . Tondon *et al.*<sup>[3]</sup> have advocated decreasing the minimum platelet count criteria from 150 to  $140 \times 10^9/L$ . Since most of the plateletpheresis donors are first-time donors, one-time donation with a platelet count between 140 and  $150 \times 10^9/L$  will not adversely affect donor's health. Even if thrombocytopenia occurs in donor, there is no risk of bleeding as platelet count remains satisfactory to maintain normal hemostasis.

Reducing the platelet count cutoff can have an adverse impact on the platelet yield of the final product as donor's preprocedural platelet count correlates with the platelet yield of the product. However, modifying the collection time and adjusting the flow rate can help in overcoming this problem.

In our study, 49.2% donors were deferred due to low platelet count. Of these 12% had a platelet count ranging

between 140 and  $149 \times 10^9/L$ . If the platelet count cutoff is relaxed to  $140 \times 10^9/L$ , our donor deferral rate will decrease from 43.2% to 40.7% [Table 2].

Therefore, if we would have relaxed Hb and platelet count cutoff for donor selection, our donor deferral rate would have decreased from 43.2% to 39.9%

Leukocytosis is defined as an increase in the WBC count to more than two SDs above the reference range or  $>11.0 \times 10^9$  cells/L. Leukocytosis due to increased absolute neutrophil count occurs in infection, inflammation, and due to certain medications. However, leukocytosis with neutrophil predominance can also occur after strenuous exercise as reported by Panch *et al.*<sup>[8]</sup> In our study, 4.9% male and 2.2% female donors were deferred due to leukocytosis [Table 1]. It is therefore important to obtain a detailed history including questions relating to strenuous exercise in donors with asymptomatic leukocytosis.

Platelets have a shelf life of only 5 days after collection. Maintaining inventory requires a sufficient number of donations. Recruitment of voluntary donors for SDP is a challenging task. The reasons are multifactorial including lack of knowledge and awareness, time constraints as plateletpheresis is a time-consuming procedure, rigid cultural beliefs, and fear of unknown. Enrollment of female donors is even tougher due to additional causes such as low weight, physiological blood loss, and poor diet.<sup>[3]</sup>

## Conclusions

There is potential for increasing the number of eligible donors if the present donor selection criteria were relaxed to a minimum Hb 12 g/dl and minimum platelet count  $140 \times 10^3/\mu l$ . If it could be confirmed by different centers that the introduction of these amendments did not compromise donor safety, the current selection criteria could be reviewed to decrease unnecessary donor deferrals. This will allow many healthy donors to contribute as valuable SDP donors without facing inappropriate donation risk thereby expanding the donor pool.

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## Conflicts of interest

There are no conflicts of interest.

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