

A Retrospective Study on Analysis of Donor Deferral Characteristics of Plateletpheresis at a Tertiary Care Hospital in North India

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Abstract: **Background:** Platelet donation is more complicated than whole blood donation. This study scrutinizes the donor deferral parameters through retrospective analysis. **Objective:** The objective is to identify the factors contributing to donor deferral in the context of apheresis derived platelets. **Methodology:** The study spanned a year, from 1st January 2022 to 31st December 2022, and was conducted in the department of Immunohaematology and Transfusion Medicine at SMS Medical College, Jaipur, Rajasthan. It included a comprehensive screening of 972 donors. **Results:** Among 972 donors, 242 (24.89%) were deferred. Most deferrals were males aged 27-35 yrs. Temporary deferrals were 96%, and the rest were permanent. Common reasons were low hemoglobin (21.07%) and ABO incompatibility (16.94%). 10.33% donors exhibited levels ranging from 11.5 to 12.4 gm%, reinforcing the relevance of this parameter. **Conclusion:** Developing countries like India face a shortage of apheresis donors. Based on our findings, we recommend revising the selection criteria of single donor plateletpheresis to suit the Indian context.

Keywords: Apheresis, deferral parameters, plateletpheresis

1. Introduction

Platelet concentrates, essential in medical treatments, can be obtained through either whole blood or the advanced process of plateletpheresis. The latter involves apheresis or preparative apheresis, wherein blood, infused with an anticoagulant solution, is drawn from a donor or patient. Subsequently, it undergoes component separation, ensuring therapeutic efficiency. Specifically, in plateletpheresis, platelets are retained, while the remaining components are returned to the individual^{[1][2][3]}.

The escalating demand for single donor platelets over time underscores the critical role of plateletpheresis^[4]. However, this method demands a more substantial commitment from donors compared to whole blood donation, primarily due to the extended procedure duration^[5]. To maintain an optimal balance between platelet yield and the safety of both patients and donors, stringent donor selection criteria are rigorously enforced. These criteria, coupled with the elevated cost per unit, contribute to a higher rate of donor deferral and attrition.

In a proactive effort to address these challenges and discover avenues for enhancing the limited pool of apheresis donors, while upholding donor safety as paramount, we conducted a meticulous retrospective analysis. Our objective was to

scrutinize the underlying causes of donor deferral and assess platelet yield parameters, thereby paving the way for informed strategies to overcome these impediments^{[6][7][8]}.

2. Materials and Method

Study Design: This retrospective study was carried out within the Immunohematology & Transfusion Medicine department at Sawai Man Singh Hospital. The study spanned a year, from 1st January 2022 to 31st December 2022.

Study Procedure: Donors were chosen according to specified criteria for the preparation of Single Donor Platelets (SDP), aligning with our hospital standard operating protocols and as per the regulations outlined in the Drugs and Cosmetics Act and Rules. The detailed criteria are provided below:

- Donor weight exceeding 60 kg.
- Donors aged between 18 and 60yrs or regular donors upto 65 years.
- Hemoglobin levels above 12.5 gm/dl.
- Platelet count above 1.5 lac/ μ l.
- A minimum gap of 28 days since the last whole blood donation, or two days since the last plateletpheresis.
- Absence of antibiotics in the last 2 weeks.

- ABO compatibility with the patient.
- No first degree relatives.
- Negative serology results for HIV, HBsAg, HCV, Syphilis, and Malaria.
- Sufficient venous access.

Sample Collection: In accordance with the regulations outlined in the Drug and Cosmetic Act by the Government of India, explicit written consent was obtained for the aforementioned study. This consent took the form of a detailed explanation of the apheresis procedure provided to donors, along with information on post-donation guidance, potential adverse reactions, mandatory testing, and, in the case of seroreactivity, referral to integrated counselling.

Blood samples from the donors were gathered for a comprehensive blood count and screening for Transfusion Transmitted Infections (TTI). Furthermore, a complete haemogram was conducted noting all the required parameters. The samples underwent testing for HIV, HBsAg, and HCV using a 4th generation enzyme immunosorbent assay (ELISA; Biorad). Additionally, a Treponema Pallidum Haemagglutination assay (TPHA; Biorad) was conducted to test for Syphilis, and a Rapid Malaria Antigen test was employed to detect malaria. Most of the apheresis procedures were conducted using the Optia Spectra continuous flow cell separator and the rest by Fresenius Kabi COM.TEC machine.

Ethical Consideration: Ethical permission was taken from Ethics Committee of SMS Medical College.

Statistical Analysis: All the data were entered and tabulated in Micro Excel software as per mentioned variables. Statistical analysis was performed using the SPSS, Version 21 (SPSS Inc., Chicago, IL, USA).

3. Results

During the study duration, a screening of 972 donors was conducted, revealing that 242 donors were deferred. This equates to a deferral rate of 24.89%. Meanwhile, a total of 730 plateletpheresis procedures were successfully carried out within the span of one year.

Among the deferred donors, a clear gender bias was evident, with a majority of them being males. Furthermore, the age bracket that predominantly experienced deferrals ranged from 27 to 35 years. These demographic details have been represented in the given Table No.1.

Table 1: Demographic correlation with population of deferred donors

	Category	Number of Deferred Donors (%)
Age	18 - 26 years	51 (21.079%)
	27 - 35 years	170 (70.24%)
	>35 years	21 (8.67%)
Gender	Male	195 (80.5%)
	Female	47 (19.5%)

Temporary deferrals dominated (shown in Figure No.1), accounting for a significant 96% of cases.

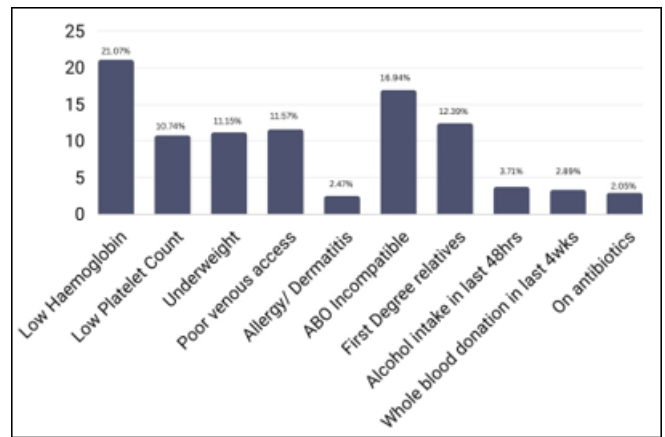


Figure 1: Percentage comparison of various causative factors for donor deferrals in plateletpheresis

The remaining 4% are categorized as permanent deferrals as shown in Figure No.2.

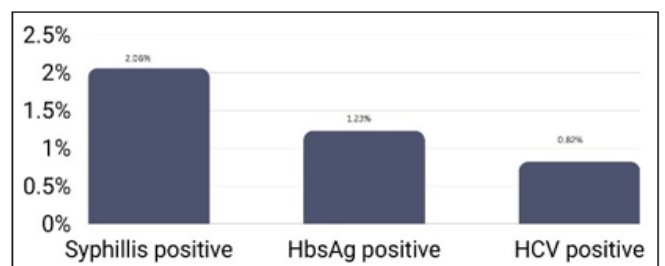


Figure 2: Percentage comparison of deferred plateletpheresis donors due to various transfusion transmitted infections

Low hemoglobin levels emerged as the most frequent cause behind the temporary deferrals, constituting around 21.07% of all deferral causes. And among these, 13.2% exhibited hemoglobin levels ranging from 11.5 to 12.4 gm%, reinforcing the relevance of this parameter. A comparative analysis based on this factor solely is given in Table No.2. Following closely was ABO incompatibility, contributing to roughly 16.94% of deferrals. The figure provides various further reasons along with percentage deferrals.

4. Discussion

Platelet transfusion serves as a crucial therapeutic intervention to mitigate the risk of morbidity and mortality in patients with severe thrombocytopenia, particularly those highly susceptible to spontaneous bleeding. The infusion of platelets is a preferred method due to its enhanced yield and reduced likelihood of alloimmunization. In such cases, Single Donor Platelets stand out as the preferred choice. This preference is rooted in the controlled nature of the process, where the extraction of platelets is tailored to donor-specific parameters such as height, weight, hematocrit, platelet count, and blood volume^[9]. But, the primary challenge in utilizing apheresis platelets stemmed from a shortage of single donor platelet contributors. This scarcity was attributed to factors such as inadequate donor education, a lack of awareness and motivation, the prolonged nature of the procedure compared to whole blood donation, donor uncooperativeness, high procedural costs, extended waiting times in government hospitals, and a general lack of safety awareness.

Complicating matters, the ineligibility of apheresis donors due to low platelet count, insufficient hemoglobin levels, underweight conditions, or underlying medical issues further compounded the challenge of selecting suitable plateletpheresis donors. In the present investigation, the rate of donor deferral stood at 24.89%, aligning closely with the findings of Pujani et al.⁵, who reported a deferral rate of 25.4%. This figure also falls within the proximity of deferral rates observed by Tondon et al.⁶ at 27.5% and Arora et al.⁷ at 28.03%. Temporary deferrals formed a significant majority, encompassing 96% of instances, while the residual 4% were classified as permanent deferrals, a pattern consistent with observations in diverse studies. Particularly within the permanent deferrals, Syphilis-positive donors played a substantial role, accounting for 2.06%, whereas HCV-positive donors made a minimal contribution at 0.86%. It's noteworthy that this observation diverges from the results reported by Arora et al.⁷ As observed in various studies, the deferred donors predominantly belonged to the youthful category, specifically under 35 years of age, constituting 91.32%. This trend aligns with the findings of Arora et al.⁷, where 82.9% of deferred donors were under 35 years. Comparable results were also noted in the investigation carried out by Pujani et al.⁵ In the current finding, the deferral of all female participants (47 individuals) predominantly resulted from insufficient hemoglobin levels. This phenomenon is likely associated with the prevalence of iron-deficiency anemia, a common occurrence among females. Existing studies also point to the limited representation of Indian females as plateletpheresis donors.

As stated before that the most common reason for deferral is low haemoglobin constituting 21.07%. Among these, 10.33% exhibited hemoglobin levels ranging from 11.5 to 12.4 gm%, underscoring the significance of this criterion. Donors identified with low hemoglobin levels should undergo counseling, treatment, and educational interventions to improve their hemoglobin levels. Among the 51 donors deferred in our study due to low hemoglobin, 25 had hemoglobin levels falling within the range of 11.5%–12.4%. Notably, Kusumgar et al.¹⁰ found no negative impact on platelet yield or donor well-being when performing plateletpheresis on 49 donors with hemoglobin levels between 11.5%–12.4%, proposing the possibility of reconsidering a significant proportion of donors with relaxed hemoglobin criteria [10]. This aligns with findings by Fraser et al.¹¹, who observed no adverse effects when adopting a hemoglobin cutoff of 11.5% among donors^[11].

Table 2: Assessing Prevalent Deferral Criteria Across Studies

Study	Deferral occurrence in donors with hemoglobin more than 12.5g/dl (%)	Deferral occurrence in donors with hemoglobin more than 11.5g/dl (%)	% of donors qualifying for donation when the hemoglobin threshold is eased to below 11.5g/dl
Pujani et al. ⁵	27.05	9.85	17.2
Tondon et al. ⁶	14	5.35	8.65
Arora et al. ⁷	20.89	12.68	8.21
Vujhini et al. ⁹	27.09	5.04	22.05
Kusumgar et al. ¹⁰	29.44	15.83	13.61
Seema et al. ¹⁴	18.96	8.62	10.34
Present Study	21.07	10.74	10.33

Our study suggests that by lowering the hemoglobin cutoff to 11.5%, approximately 10.33% of donors could be reintegrated into the donor pool. This phenomenon can be explained by the minimal decrease in red cell count observed in apheresis, facilitated by the use of advanced equipment and reduced tubing loss. Careful enlistment of donors with borderline anemia can be conducted safely, providing an alternative donation avenue for volunteer blood donors, particularly women, who would otherwise be excluded [12].

The second most prevalent reason for deferral, accounting for 16.94%, was ABO incompatibility which was owing to the fact that our blood bank does not utilise platelet additive solutions due to heightened costs and limited availability. Importantly, this aspect differed from the observations of Brijesh et al.⁴, who reported a lower ABO incompatibility rate at 5.8%. The third most frequent reason for deferral was the presence of first-degree relatives of the patient to avoid HLA isoimmunization. Therefore, it is essential to launch extensive awareness campaigns emphasizing that first-degree relatives and ABO incompatible donors are suboptimal choices. Additional factors leading to deferral included challenges with venous access (11.57%), being underweight (11.15%), and presenting with low platelet levels (10.74%).

5. Conclusion

In emerging nations such as India, the predominant reliance on replacement blood donations rather than voluntary contributions perpetuates a persistent shortage of apheresis donors. This unique circumstance prompts a thoughtful reevaluation of the selection criteria for plateletpheresis donors. A particular focal point is the criteria concerning the minimum pre-procedure hemoglobin level, currently stipulated above 12.5 g/dl.

Furthermore, the necessity for a comprehensive revamping of awareness programs becomes apparent. These initiatives should emphasize the crucial information that first-degree relatives and individuals with dissimilar blood groups are not the optimal candidates for plateletpheresis donation. Cultivating a broader understanding among the public about the intricacies of suitable donors is pivotal in addressing the perpetual shortage of apheresis donors. And also not to forget the use of Platelet Additive Solution (PAS), which is recommended to overcome the ABO incompatible deferrals.

Embracing these recommendations holds the potential to yield far-reaching benefits, notably in significantly reducing the deferral rate for apheresis. It's noteworthy that temporary deferrals currently contribute substantially to the overall deferral causes. By fostering awareness and revisiting the criteria in line with the specific needs of the Indian scenario, we can collectively endeavor to enhance the pool of potential plateletpheresis donors, contributing to a more sustainable and robust blood donation system in the region.

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