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Original Article

Frequency of Adverse Effects Associated with Platelet Apheresis in Donors; An Experience in a Tertiary Care Hospital

Neelam Mazhar¹
 Sidra Hareem²
 Ayesha Khanum³
 Arsalan Aftab⁴
 Faouzia Aamir⁵
 Saima Farhan⁶

Abstract

Background: Platelet apheresis involves taking blood from the donor, processing it into components, separating the platelets and returning the blood back to donor. It is a safe procedure, but it can still be associated with certain adverse events that requires attention.

Objective: To assess the frequency of adverse effects associated with platelet apheresis in donors at a tertiary care hospital.

Materials and Methods: This observational cross-sectional study was conducted at the Department of Hematology and Transfusion Medicine, Children's Hospital and University of Child Health Sciences, Lahore, from September to December 2024, included 80 healthy donors undergoing platelet apheresis. The data was recorded on demographics, medical history, and occurrence of adverse events using a self-designed proforma. The frequencies of categorical variables were calculated. The association between gender and frequency of adverse events was evaluated using a chi-square test.

Results: The donor population was predominantly male (95%) with a mean age of 28.9 years. The overall adverse event rate was 10%, in which tingling sensation (7.5%) was most common local reaction followed by loss of consciousness and dizziness (3.8% each) and hypotension (2.5%), that were most common systemic reactions. The chi-square reported ($p=0.494$), which indicated no significant association between gender and occurrence of adverse events.

Conclusion: Platelet apheresis is generally safe, with low incidence of mild adverse reactions that can be managed through comprehensive donor monitoring. Improvement in donor safety SOP's is essential to maintain the safety profile of platelet apheresis.

Keywords: Platelet apheresis, adverse events, local adverse reactions, systemic adverse reaction.

¹Assistant Professor hematology
 University of child health sciences
 Lahore

²Assistant Professor hematology
 children's hospital Lahore

³Assistant Professor Paediatric
 hematology

Children's hospital Lahore

⁴Medical lab technologist

Children's hospital Lahore

⁵Associate Professor hematology
 children's hospital Lahore

⁶Professor of Paediatric hematology
 children's hospital Lahore

Address for Correspondence

Dr Neelam Mazhar
 Assistant Professor hematology
 University of child health sciences Lahore
 neelam_mazhar1@hotmail.com

Introduction

Platelet apheresis is procedure which takes blood from the donor, then process it into its components, separates the platelets and then returns the blood back to donor. It is a complex process that requires specialized equipment and professional staff. All donors undergo a detailed pre-donation screening process which includes general physical examination, history of major illnesses, past transfusions, vaccinations, blood donations, medications, vital signs assessment, platelet count and hematocrit readings.¹ It includes the process of withdrawing blood from the donor through a sterile tube to a cell separator machine, where the platelets are separated in an ACD-A coagulant contain sterile bag while other components, along with hydration fluid, are returned back to the donor. This usually takes about 60-

90 minutes.² This essential procedure supplies platelets necessary for patients with cancer, transplants, and patients with bleeding disorders, and also assists surgeries and trauma management by promoting rapid and effective hemostasis.³ Apheresis procedures are usually well-tolerated in the donors; adverse reactions and complications can happen, which usually involve tingling, numbness, muscle cramps, etc.⁴ These side effects are mostly mild and short. Adverse reactions can be divided into local reactions and systemic reactions.⁵ The most common local adverse reaction from platelet apheresis in donors occurs at the needle insertion site, often resulting in minor, self-limited issues such as bruising (ecchymosis), hematoma, pain at the puncture site, tingling or numbness, vein irritation, and allergic reactions like redness and itching.⁶ Most local reactions resolve independently or with minimal intervention.⁷

Systemic adverse effects, which, though less common than local reactions, can affect multiple organ systems, which includes citrate toxicity, a result of the anticoagulant binding to calcium in the blood, can cause symptoms like tingling, chill etc.⁸ Vasovagal reactions, triggered by stress or anxiety, may result in dizziness,

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fainting, or nausea due to a sudden drop in blood pressure and heart rate.⁹ Allergic reactions, though rare, can range from mild itching and hives to severe anaphylaxis, requiring immediate intervention.¹⁰ Other common systemic reactions include hypotension, a reduction in blood volume, because of fluid shifts during the operation, or due to vasovagal centers' control over blood vessels and fatigue.⁷ These reactions can be reduced by carefully monitoring the vital sign and keeping proper hydration level of donor.¹¹

Platelet apheresis is critical for providing lifesaving platelet transfusions to patients with various medical conditions, including cancer and bleeding disorders¹². However, the procedure is associated with potential adverse effects, ranging from local to systemic reactions. This type of study on donor safety has not been done in any pediatric care setting. Gaining comprehension of these occurrences can yield valuable information for improving the procedures of platelet donation.

Methodology

This observational cross-sectional study was conducted at the Department of Hematology and Transfusion Medicine at Children Hospital and University of Child Health Sciences Lahore from September 2024 to December 2024. After approval from IRB (No. 752/SAHS), a total of 80 platelet apheresis procedures were performed on TRIMA Accel LPL77378062, a single-needle intermittent flow cell separator. All donations were collected using a 17-gauge needle inserted into a vein in the antecubital fossa, following sterile procedures. Donors were selected as per the set criteria for single donor platelet preparation according to DGHS guidelines. Hemoglobin should be 12.5g/dl.¹³ Hematocrit should be less than 33%. Weight should be 60 kg or more. Age should be between 18 to 50 years. Platelet count should be greater than 200,000 / μ l.¹⁴

Donors must be in good general health and pass a pre-donation health screening, including a physical examination and medical history review. The interval between procedures should be at least 48 hours. A donor shall not undergo the procedure more than 2 times in a week or 24 times in a year. Donors who had taken aspirin within the last 36 hours, tested positive for HIV, hepatitis B, syphilis, HCV, or malaria, or were currently ill were deferred. Additionally, those who had received attenuated live viral vaccines (e.g., smallpox, measles, influenza) had to wait two weeks before

donating. Permanent deferral applied to individuals who had received nonhuman animal transplants of cells or tissues.

The data was entered and analyzed using IBM-SPSS 23.0 software. The continuous variables (Age, weight etc.) were expressed as Mean $\pm$ SD, whereas categorical variables in the form of frequencies and percentages. Chi-square test was employed to test association between categorical variables. A p-value less than 5% was considered as statistically significant.

Results

In total, 80 donors undergoing platelet apheresis were included in the study. Out of these, 95% were male and 5% were female, resulting in a male-to-female ratio of 19:1. Results obtained from the demographic analysis of the potential donor showed a mean age of

28.9 years (SD = 5.826) for the donors. The vital signs were normal, and the mean value for pulse rate was 71.59 beats-per-minute (SD = 2.05), for body weight was 65.2 kg (SD= 8.92), for respiratory rate was 40 breaths-per-minute (SD = 0.68), and for body temperature was 98.4°F (SD = 0.18). B positive was the dominant blood group among the donors, which constitutes 45% followed by O positive, 28.7%. Only three donors (3.8%) from the total number of donors had a previous history of blood transfusions. Very few donors (1.3%) have a deferred history related to incidents of needle pricks, but none have a history related to tattoos and body pierces. Out of 80 donors, just 8 donors (10%) showed adverse reactions, and 90% of the donors completed the process successfully. The apheresis procedures yielded few local side effects in the donating population. Of note is that no episode of bruising (ecchymosis) or hematoma formation occurred. The tingling sensation experienced by 6 of the Donors accounted for 7.5% of the 80-donating population., as shown in figure 1.

The incidence of systemic adverse events was comparably low among the donors. However, there were no adverse events related to fever, convulsions, and tetany. One donor (1.3%) had pallor, while two donors (2.5%) had nausea, weakness, sweating, and vomiting. Three donors (3.8%) suffered dizziness and loss of consciousness. Two donors (2.5%) had hypotension. The result of this finding implies that while most of the donors had responded well to the

procedure, a few suffered from mild to moderate systemic reactions as shown in figure 2.

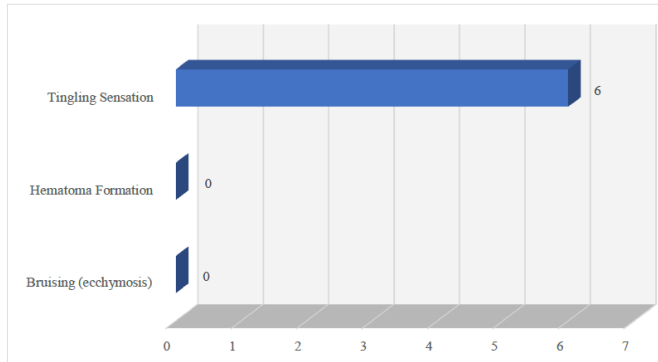


Figure 1: Frequency of Local Adverse Reactions.

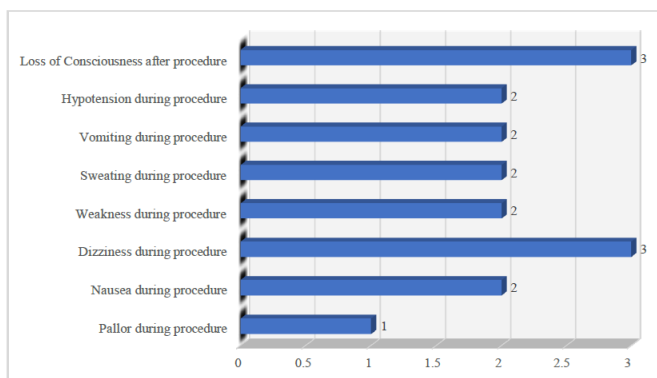


Figure 2: Frequency of Systemic Adverse Reactions.

For determining the association between gender and the occurrence of adverse events during the platelet apheresis process, the chi-square test for independence was performed. The result reveals that there is no significant relationship between gender and the occurrence of adverse events ($\chi^2 = 0.468$, $p = 0.494$). Of the 80 participants, 8 males (10.5%) experienced adverse events, while no females (0%) did. The majority of participants (90%) did not experience adverse events.

Discussion

While donors typically tolerate apheresis procedures well, adverse reactions and complications can occur. The purpose of this study was to assess safety and adverse events associated with platelet apheresis donation in a tertiary care facility, taking into account local as well as systemic reaction. In the light of this cross-sectional study, we come to know that 95% of the total donor population were young men who have undergone platelet apheresis. Males have higher physiological characteristics, blood volume, and hemoglobin levels than females, and they are less prone

to deferrals, which explains the higher number of male donors. Stable vital signs and hematological parameters of the donor throughout the procedure showed that this procedure is safe. In this case study, the overall adverse event rate occurred at 10%, which shows a little more than the 6.06%¹¹, and 3.7% reported by.¹⁵ The incidence of local adverse events was notably low, with tingling sensation being the only reported local reaction (7.5%). This is comparable to the findings of¹⁵, who reported vascular injuries in 1.40% of cases. The absence of bruising and hematoma formation in the study which indicates more effective standards for donor puncture and care protocols have been put in place.

In this study, the most common systemic adverse reactions reported were dizziness and loss of consciousness occurring at the same rate of 3.8% followed by nausea, weakness, sweating, hypotension and vomiting which accounted for 5% of reactions, however pallor was the least reported adverse event (1.3%). These results are close to those of¹¹ where the main adverse reactions were vasovagal reactions and citrate toxicity. The majority of patients (90%) experienced no adverse events. A chi-square test for independence found no statistically significant correlation between the gender and adverse reactions during platelet apheresis. These results show that platelet apheresis is a safe procedure without any connection to gender association. In summary, platelet apheresis procedures are generally safe, but they are associated with adverse events. The risks with can be reduced by careful monitoring of donors, improving the training of staff and by increasing the comfort level of donors by proper hydration and vitals check.

Conclusion

Platelet apheresis is generally considered to be a safe procedure, with a relatively low incidence of mild adverse reactions that can be adequately managed through careful monitoring and care of donors. Continuing improvement in practices focused on maintaining donor safety is vital for maintaining the safety profile of platelet apheresis.

Limitations: The primary limitation of this study was its short time duration. A longer time duration can further improve the safety of this procedure.

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