Research Article

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Journal of Clinical and Molecular Pathology

2022
Vol.6 No.3:001

# Frequency and Type of Common Adverse Donor Reactions in Apheresis Donors-An Audit of a North Indian Hospital

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**Received date:** February 23, 2022, Manuscript No. IPJCMPY-22-12531; **Editor assigned date:** February 28, 2022, PreQC No. IPJCMPY-22-12531 (PQ); **Reviewed date:** March 15, 2022, QC No IPJCMPY-22-12531. **Revised date:** April 25, 2022, Manuscript No. IPJCMPY-22-12531 (R); **Published date:** May 2, 2022, DOI: 10.36648/IPJCMPY/22.6.001

**Citation:** Chhikara A (2022) Frequency and Type of Common Adverse Donor Reactions in Apheresis Donors-An Audit of a North Indian Hospital. J Clin Mol Pathol. Vol:6 No:3

## Abstract

**Background:** Safe blood starts with a safe donor. Most donors tolerate blood donations very well but occasionally Adverse Events (AEs) may occur.

**Aim:** The aim of present study was to assess the frequency and type of adverse events occurring in aphaeresis donors at our hospital from august 2018 to April 2019, and to assess the practices which could help to minimize these adverse events.

**Design:** Retrospective single center study.

**Materials and Methods:** This was a retrospective single center study of all adverse events related to all apheresis donations between August 2018 and April 2019. All donors underwent complete hemogram and TTI testing prior to donation. Post donation the donors were observed for any adverse event. Statistical analysis: Statistical analysis was done doing SPSS 20.

**Results:** A total of 395 plateletpharesis procedures were analyzed during the duration of this study. 24 donors had adverse reactions. A total of 29 Adverse Events (AEs) were noticed. The rate of vascular injuries, citrate reaction and presyncope/syncope were 8/395 (2.0%), 14/295 (3.5%) and 01/395 (0.2%).

**Conclusion:** Apheresis is safe and mild AEs can be reduced by meticulous donor vigilance, adequate training of the technical staff and reassuring the donor and mild medical intervention

**Keywords:** Adverse event; Apheresis; Transfusion; Citrate reaction

## Introduction

Safe blood starts with a safe donor. Blood transfusion services all over world exclusively depend upon healthy donors. To motivate donations initially and to retain them, it is essential that donation experience is safe and pleasant. Therefore, donor care is a critical factor to ensure safe blood and safe transfusion practices.

Most donors tolerate blood donations very well but occasionally Adverse Events (AEs) may occur. These adverse events can negatively affect donor retention and recruitment. Many authors report that apheresis/plateletpharesis is a safer procedure as compared to whole blood donation and is associated with less frequent adverse donor reactions [1-2]. The frequency of adverse donor reaction in apheresis ranges from 0.32 to 6.8% [3-4].

The adverse reactions can be divided into local and systemic and vary in degree from mild to severe. The aim of present study was to assess the frequency and type of adverse events occurring in aphaeresis donors at our hospital from August 2018 to April 2019, and to assess the practices which could help to minimize these adverse events.

## Materials and Methods

This was a retrospective single center study of all adverse events related to all apheresis donations between August 2018 and April 2019. For plateletpharesis platelet concentration system (Trima Accel automated blood collection system) was used. The donor selection criteria used for apheresis apheresis included:

- weight >50 kg
- Age 18-65 yrs.
- At. Least 3 months from last blood donation/three days from last aphaeresis
- Hemoglobin >12.5 g/dl
- Platelet count >1.5 × 1011/microl.
- Absence of any illness
- No consumption of non-steroidal anti-inflammatory drugs in last seven days.
- Negative test for HIV, Hepatitis B, Hepatitis C, Syphilis and malaria.
- Adequate venous access

The blood samples of donors were collected for Complete blood counts as well as for Transfusion Transmitted Infections (TTI). Complete hemogram was done using Sysmex.

The samples were tested for HIV, HbsAg, and HCV using 4th generations Enzyme Linked Immune Sorbent Assay (ELISA), TPHA kit for syphilis and rapid malaria antigen test for malaria. Donors who were fit as per the screening criteria mentioned above were called for apheresis the next day. The procedure was done using Trima Accel automated blood collection system. All adverse events were noticed by the staff present and documented using the standard format of the department. The adverse events were classified as:

- Vascular Injury
- Citrate Reaction
- Presyncopal/syncopal

The vascular injuries included pain (mild/severe) at phlebotomy site, hematoma, multiple picks and arterial puncture.

Citrate reaction included mild (circumoral paresthesia, tingling, and numbness) and severe (tetany) Presyncopal/ syncopal reactions included nausea, vomiting, faintness/ syncope/sweating

### Statistical analysis

Statistical analysis was done doing SPSS 20.

## Results

A total of 395 plateletpharesis procedures were analyzed during the duration of this study. 24 donors had adverse reactions. A total of 29 Adverse Events (AEs) were noticed. All AEs were divided into vascular injuries, citrate reactions and presyncope/syncope. The rate of vascular injuries, citrate reaction and presyncope/syncope were 8/395(2.0%), 14/295(3.5%) and 01/395 (0.2%). Three donors had hematoma, mild pain as well as multiple pricks. Table 1 shows the rate of vascular injuries, citrate reactions and presyncopal/syncopal reactions.

**Table 1:** Incidence of adverse events AEs=24/395 donors (6.0%).

| Adverse Events | First time (n=287) | | Repeat donations (n=108) | |
|---|---|---|---|---|
| | Number | Percentage | Number | Percentage |
| Vascular injuries | | | | |
| Pain | | | | |
| Mild | 04 | 1.4 | | |
| Severe | | | 01 | 0.9 |
| Hematoma | 03 | 1.0 | | |
| Multiple pricks | 05 | 1.7 | 01 | 0.9 |
| Arterial puncture | | | | |
| Citrate reaction | | | | |
| Circumoral paresthesia | | | 01 | 0.9 |
| Tingling | 08 | 2.8 | 02 | 1.8 |
| Numbness | 02 | 0.7 | | |
| Tetany | 01 | 0.3 | | |
| Presyncopal/syncopal | 01 | 0.3 | | |

Among the vascular injuries hematoma occurred in 03/24 donors, pain occurred in 05/24 donors and multiple pricks were needed in 06/24 donors. Among the citrate reactions tingling was most common noticed in 10/24 donors. One donor had circumoral paresthesia. Two donors complained of numbness. Severe citrate reaction in form of tetany was noticed in one donor. Only one donor developed presyncopal/syncopal event presenting as sweating.

Table 2 shows the association of AEs with split in respect to weight, Age, duration of procedure and volume of ACD. The AEs occurred in 19 in first time donors and 5 repeat donors. Among the 24 donors manifesting AEs 15 weighed <80 kgs and 21 were

<40 years of age. 22 of 24 AEs occurred in duration of procedure lasting <60 min. Only two donor had AEs with procedure lasting <60 min. 11 out of 24 donors manifesting ACD had ACD volume transfused >250 ml. Tingling was the most common presentation in these donors.

**Table 2:** Association between the adverse events identified and the variables related to the donor and plateletpharesis procedure.

| Variables | AE present (n=24) | | AE absent (n=371) | |
|---|---|---|---|---|
| | N | % | N | % |
| **Body weight** | | | | |
| <80 kg | 15 | 62.5 | 235 | 63.3 |
| ≥ 80 kg | 09 | 37.5 | 136 | 36.7 |
| First time/repeat donation | | | | |
| FT | 19 | 79.2 | 268 | 72.2 |
| RPT | 05 | 20.8 | 103 | 27.8 |
| Age range | | | | |
| < 40 years | 21 | 87.5 | 368 | 99.1 |
| ≥ 40 years | 03 | 12.5 | 24 | 0.9 |
| Duration of procedure | | | | |
| <60 min | 22 | 91.6 | 361 | 97.3 |
| >60 min | 02 | 8.4 | 10 | 2.7 |
| ACD volume | | | | |
| <250 ml | 11 | 45.8 | 350 | 94.3 |
| ≥ 250 ml | 13 | 54.2 | 21 | 5.7 |

All AEs were noticed during the procedure except one donor who complained of severe pain after the procedure (Table 3).

**Table 3:** Adverse Events during and after plateletpharesis procedure.

| **Total AEs (n=29)*** | |
|---|---|
| Vascular | |
| During procedure | 13 |
| After procedure | 01 |
| Total | 14 |
| Citrate reaction | |
| Mild-moderate | 13 |
| Severe-tetany | 01 |
| Total | 14 |
| Presyncopal/syncopal | 01 |

Three donors had hematoma, mild pain as well as multiple pricks.

## Discussion

Donor related local reactions often present as local pain/ hematomas. These usually occur due to faulty phlebotomy technique leading to extravasation of blood. Present study reported 3.5% vascular injuries, including 0.7% due to hematomas and 1.2% due to pain. Three donors had hematomas, multiple pricks as well as complaints of pain. This again is due to faulty phlebotomy technique. These findings are similar to as observed by Philip et al and Barbosa [5-6].

Citrate reaction is common in platelet pharesis and is usually mild comprising of perioral paresthesia, tingling or numbness. Although mild these have potential for severe injury to the donor. Factors that influence CR in donor include hyperventilation leading to alkalosis, type, rate and amount of anticoagulant solution used and donor albumin levels prior to the procedure [7-8].

These mild reactions are often self-limiting [1]. Few donors develop severe citrate reaction presenting as tetany. Single donor developed tetany in current study. He also had >250 ml of ACD transfused. The reason for hypocalcemia during apheresis is chelation of ionized calcium by citrate present in ACD [9]. In present study 3.5% citrate reactions were noticed, tingling being most common, seen in 2.5% donors. The findings are similar to as noticed by Dogra [10]. The treatment of CR is simple if reactions are identified early.

Systemic reactions including presyncopal/syncopal events are usually triggered by anxiety or apprehension of needle prick [5]. The donor presents with sweating, dizziness or hypotension. In our study single donor had PS/S reactions presenting as sweating (0.2%). This is similar to as observed by Philip et al and McLeod [3-5].

In such cases procedure should be paused immediately. Additional treatment of vasovagal reaction includes placing the donor in Trendelenburg position, applying cold sponges to head and neck of donor and reassuring the donor. The overall rate of mild adverse reaction in our study was 5%. This is similar to as observed by Dogra et al. and Arora [11].

Overall apheresis procedure has less severe reactions compared to whole blood donation. The AEs are usually mild and easy to manage (Table 4).

**Table 4:** Comparison of adverse events in various studies.

| Type of adverse events | Present study | Dogra ( 2016) | Barbosa (2014) | Arora ( 2016) | Philip ( 2013) | McLeod ( 1998) |
|---|---|---|---|---|---|---|
| Hypocalcemia | 3.5% | | 2.7% | | 0.9% | 0.39 |
| Vascular injuries | 3.5% | 1.2% | | 1.4% | | 1.15 |
| Hematoma | 0.7% | | 1.9% | | 1.6% | |
| Vasovagal reaction | 0.2% | | 0.8% | | 0.09% | 0.39 |
| MildAEs(Vascular injuries and mild citrate reactions | 5.0% | 5.86% | 4.5% | 4.4% | 2.6% | 2.18 |

## Conclusion

Apheresis is safe and mild AEs can be reduced by meticulous donor vigilance, adequate training of the technical staff and reassuring the donor and mild medical intervention. Proper donor information materials should be provided in order to retain the donor and allay the donor apprehension.

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