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RESEARCH ARTICLE

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# Delayed adverse events in male plateletpheresis donors: Initial insights on donor safety

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**Abstract**

**Background:** Minimal information is available regarding delayed adverse donor events (D-ADEs) in plateletpheresis donors. Proactive follow up of donors for D-ADEs is not done routinely by BTS. The aim of this study was to analyze frequency and type of D-ADEs and its correlation with contributory factors if any.

**Methods:** In this prospective observational study all eligible donors were contacted by telephone twice and asked about general wellbeing and questions specific to adverse donor events (ADEs). Donors were called at 24 hours and 2 weeks after donation. The ADEs were categorized in accordance with the International Society of Blood Transfusion standard guidelines.

**Results:** A total of 531 donors were analyzed in the study. D-ADEs were more common as compared to immediate ADEs (I-ADEs) (19.21% vs 5.46%, $P < .0001$). The most common D-ADEs were bruises (7.34%) and sore arms (3.58%). Localized D-ADEs in form of bruise and hematomas were more frequent as compared to systemic D-ADEs like fatigue and vaso-vagal reactions (16.01% vs 3.20% $P < .0001$). Repeat donors had a lower incidence of systemic D-ADEs (1.61% vs 6.96%, $P = .001$). Donors with weight ≤75 kg and platelet count $\leq 230 \times 10^3$ μL were more prone to systemic D-ADEs ($P < .05$). Citrate toxicity was more common in donors with weight ≤ 75 kg ($P = .002$).

**Conclusions:** Plateletpheresis procedures are relatively safer without any sequelae. D-ADEs are more common than I-ADEs. Localized D-ADEs are more frequent than systemic D-ADEs. First-time donors are more prone to D-ADEs than repeat donors.

**KEYWORDS**

apheresis donor safety, delayed adverse donor events, hematoma, plateletpheresis, vaso-vagal reactions

## 1 | INTRODUCTION

Apheresis platelets (APs) allow an adequate dose of platelets to be collected from a single donor.[1] It has become a regular activity to fulfill the increasing demands of platelets. APs have significantly reduced the hazards associated with multiple donor exposure such as bacterial contamination, transfusion transmitted infections and alloimmunization risk.[2]

AP donors are prone to anticoagulation related side effects of citrate toxicity in addition to adverse donor events (ADEs) seen in whole blood (WB) donors.[3] Many studies have focused on immediate ADEs (I-ADEs, occurring from the start of the procedure until the donor departs from the apheresis center) and post-donation electrolyte changes but ADEs occurring after the AP donor has left the Blood Transfusion Services (BTS), that is, delayed ADEs (D-ADEs)

  

have not been studied and reported in published literature yet.[4-8]

AP and WB donations are completely different procedures and may have different immediate and delayed ADE profiles that need further exploration. Proactive follow up of donors for D-ADEs is not done routinely by the BTS.

The present study analyses the spectrum of ADEs in AP donors with a focus on D-ADEs.

## 2 | MATERIALS AND METHODS

This prospective observational study was done at a tertiary care hospital after due approval of the Institutional Ethics Committee. The study was carried out over a period of 9 months from October 2018 to June 2019. All consecutive AP donors who meet the eligibility criteria were included in the study after informed consent. All plateletpheresis procedures were done on either Haemonetics MCS+ (Braintree, Massachusetts) or Trima Accel (Terumo BCT, Lakewood, Colorado). All ADEs were categorized in accordance with the criteria of the standard for surveillance of complications related to blood donation by the working group on donor vigilance of the International Society of Blood Transfusion working party on haemovigilance.[9] Data were collected on donor demographics, laboratory tests, procedure details, details of any ADEs which occurred during or post-procedure. Subsequently, telephonic interviews of AP donors were conducted on two occasions by a Medical Resident. The first call was made at 24 hours of AP donation, while the second call was made 2 weeks later. The donors were asked regarding their wellbeing followed by questions specific to ADEs from a structured questionnaire which had been self- validated (Supporting Information). If the donor had any D-ADEs then proper advice and counseling were provided to the donor.

## 3 | STATISTICAL ANALYSIS

The primary data was directly documented on spreadsheets using Microsoft Excel. IBM SPSS was used for the statistical analysis (IBM SPSS for Windows, Version 23.0. Armonk, New York: IBM Corp.). The overall analysis of the data was descriptive with results presented as a percentage for categorical data. Different variables are compared using the chi-square test with two-sided Fisher exact test in cross tables. A $P$-value of <.05 was considered to be statistically significant.

AP donors were categorized on the basis of the apheresis system used (Trima Accel or MCS+), duration of the AP procedures (≤60 or ≥ 61 minutes), volume of ACD used (≤300 or ≥301 mL), first-time vs repeat donors, age (18-24, 25-35, and ≥36 years), hemoglobin (12.5-14, 14.1-16, and ≥ 16.1 g/dL), weight of the donor (≤75 or ≥ 76 kg) and platelet counts of the donor (≤230 or ≥231 × $10^3$/μL) for the purpose of analysis.

## 4 | RESULTS

A total of 584 AP donors consented to participate in the study initially but 53 donors did not respond on follow up and were excluded from the study, thus a total of 531 donors were evaluated for the analysis of ADEs. All the AP donors were males and the majorities were repeat donors (70.24%). The median age, weight, and hemoglobin of the donors were 29 years, 75 kg and 15.3 mg/dL, respectively. Donor's demographics and plateletpheresis procedure details in are shown in Table 1 and Figure 1, respectively.

### 4.1 | Immediate adverse donor events

Mild citrate toxicity in the form of circumoral/digital paresthesiae and a feeling of vibrations was the most common I-ADE seen in 274 (51.6%) donors. Paresthesiae were more common with MCS+ as compared to Trima Accel apheresis system (70.59% vs 34.06%, $P < .001$). Paresthesiae were more commonly reported by donors ≤75 kg as compared with donors ≥76 kg (62.06% vs 39.76%, $P < .001$). Donors whose procedures lasted for more than 60 minutes (69.49% vs 32.82%, $P < .001$) and required more than 300 mL of anticoagulant (72.18% vs 33.57%, $P < .001$) were associated with a higher incidence of paresthesiae. Being so common, and often confused with the transmission of the vibrations from the centrifuge of the apheresis equipment, paresthesiae were not included in the overall calculation of incidence of the I-ADEs.

A total of 29 (5.46%) AP donors experienced I-ADEs (Table 2). The most common I-ADEs were hematomas (n = 19), muscular spasms (n = 6) and vaso-vagal reactions (VVRs) (n = 4).

### 4.2 | Delayed adverse donor events

A total of 102 (19.21%) donors reported 114 D-ADEs. Majority of donors (88.24%) reported a single D-ADE while few (11.76%) reported more than one D-ADE. Bruising was the most common D-ADE (n = 39) followed by sore arms (n = 19), fatigue or non-specific weakness (n = 12), delayed bleeding from the site of phlebotomy (n = 12), allergic events or itching at the phlebotomy site (n = 11), delayed hematoma formation (n = 10), delayed paresthesiae (n = 6), delayed VVRs (n = 3) and delayed muscular spasms (n = 2). Distribution of D-ADEs is shown in Table 3.

Bruising was noticed by 7.34% (n = 39) of the AP donors and included donors with both immediate and delayed hematomas.

**TABLE 1** Plateletpheresis donor's demographics and hematological parameters

| | Age (years) | | | Weight (kg) | | Hemoglobin (g/dL) | | | Platelet count | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 18-24 | 25-35 | ≥36 | ≤75 | ≥76 | 12.5-14 | 14.1-16 | ≥16.1 | ≤230 × $10^3$/μL | ≥231 × $10^3$/μL |
| Overall (n = 531) | 137 (25.80%) | 292 (54.99%) | 102 (19.21%) | 282 (53.11%) | 249 (46.89%) | 48 (9.04%) | 364 (68.55%) | 119 (22.41%) | 253 (47.65%) | 278 (52.35%) |
| First-time donors (n = 158) | 64 | 68 | 26 | 96 | 62 | 12 | 105 | 41 | 76 | 82 |
| Repeat donors (n = 373) | 73 | 224 | 76 | 186 | 187 | 36 | 259 | 78 | 177 | 196 |

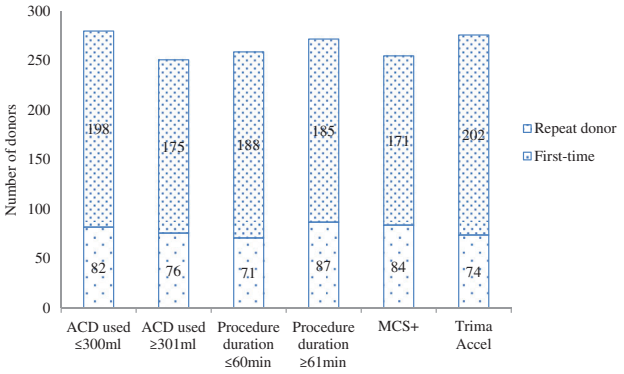


**FIGURE 1** Plateletpheresis procedure details

**TABLE 2** Incidence of immediate adverse donor events

| | Hematomas | Spasms | VVRs |
|---|---|---|---|
| Overall (n = 531) | 19 (3.58%) | 6 (1.13%) | 4 (0.75%) |
| First-time donor (n = 158) | 8 | 3 | 2 |
| Repeat donor (n = 373) | 11 | 3 | 2 |
| *P* value | .231 | .501 | .688 |
| Weight ≤ 75 kg (n = 282) | 8 | 6 | 3 |
| Weight ≥ 76 kg (n = 249) | 11 | 0 | 1 |
| *P* value | .328 | .044* | .720 |
| Platelet count ≤ 230 × $10^3$ μL (n = 253) | 6 | 6 | 2 |
| Platelet count ≥ 231 × $10^3$ μL (n = 278) | 13 | 0 | 2 |
| *P* value | .153 | .023* | .999 |

Abbreviation: VVRs, vaso-vagal reactions.
*$P < .05$.

Nineteen (3.58%) donors complained of sore arms. No significant correlation was found between sore arms and donor or procedure parameters.

Fatigue or non-specific weakness was experienced by 2.26% (n = 12) donors. It was more common in donors weighing ≤75 kg (3.56% vs 0.80%, $P = .034$) and first-time donors (5.70% vs 0.80%, $P < .001$). It was also common in donation procedures longer than 60 minutes (3.68% vs 0.77%, $P = .037$). Few donors (n = 4) had undertaken strenuous physical activity including sports or smoked immediately after the donation which lead to post-donation weakness.

Delayed bleeding from the site of phlebotomy was noticed by 2.26% (n = 12) donors. Three donors told that they removed the adhesive band immediately after leaving the BTS, this lead to slight bleeding. Two donors gave a history of baggage lifting

**TABLE 3** Incidence of delayed adverse donor events

| | | Localized D-ADEs | | | | | | | Systemic D-ADEs | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **AP donors** | **Overall** | **Bruising** | **Sore arms** | **Delayed bleeding** | **Allergic events** | **Hematoma** | **Paresthesiae** | **Overall** | **Fatigue** | **VVRs** | **Spasms** | **Overall** |
| Overall (n = 531) | 102 (19.21%) | 39 (7.34%) | 19 (3.58%) | 12 (2.26%) | 11 (2.07%) | 10 (1.88%) | 6 (1.13%) | 85 (16.01%) | 12 (2.26%) | 3 (0.56%) | 2 (0.38%) | 17 (3.20%) |
| First-time donors (n = 158) | 35 | 12 | 5 | 3 | 3 | 2 | 2 | 24 | 9 | 2 | 0 | 11 |
| Repeat donors (n = 373) | 67 | 27 | 14 | 9 | 8 | 8 | 4 | 61 | 3 | 1 | 2 | 6 |
| *P* value | .264 | .886 | .738 | .999 | .999 | .775 | .999 | .738 | <.001* | .425 | .986 | .001* |
| Weight ≤ 75 kg (n = 282) | 56 | 16 | 11 | 8 | 3 | 5 | 5 | 41 | 10 | 3 | 2 | 15 |
| Weight ≥ 76 kg (n = 249) | 46 | 23 | 8 | 4 | 8 | 5 | 1 | 44 | 2 | 0 | 0 | 2 |
| *P* value | .686 | .116 | .670 | .341 | .083 | .999 | .279 | .326 | .034* | .298 | .561 | .003* |
| Platelet count ≤ $230 \times 10^3$ μL (n = 253) | 51 | 14 | 12 | 4 | 5 | 3 | 5 | 38 | 9 | 2 | 2 | 13 |
| Platelet count ≥ $231 \times 10^3$ μL (n = 278) | 51 | 25 | 7 | 8 | 6 | 7 | 1 | 47 | 3 | 1 | 0 | 4 |
| *P* value | .596 | .127 | .484 | .318 | .883 | .422 | .175 | .554 | .055 | .929 | .453 | .016* |

*Note:* Cumulative and individual D-ADEs percentage may differ as 11.76% donors reported more than one D-ADEs.

Abbreviation: D-ADEs: Delayed adverse donor events.

*Statistically significant *P*-value.

before bleeding. Rest of the donors (n = 7) did not recall any relevant history before the bleeding episode. Delayed hematoma formation was reported by 1.88% (n = 10) donors. Four donors said that they lifted a heavy bag or did a strenuous exercise before hematoma formation. Rest of the donors did not recall any preceding event before hematoma.

Allergic events or itching at the phlebotomy site was reported by 2.07% (n = 11) donors. Four donors were first-time donors while seven were repeat donors. None of the donors gave any history of significant allergies in the past. Among the repeat donors, one donor remembered some allergic reaction during a previous blood donation.

Delayed paresthesiae were reported by six donors (1.13%). It was only reported in donation procedures longer than ≥61 minutes (2.21%, $P = .031$). It was more common in donors with platelet counts $\leq 230 \times 10^3/\mu L$ (1.98% vs 0.36%, $P = .175$), using more than ≥301 mL ACD (1.77% vs 0.40%, $P = .284$) and in donors with body weight ≤75 kg (1.77% vs 0.40%, $P = .279$).

Delayed VVRs were reported by 0.56% (n = 3) donors. All the VVRs occurred within 6 hours of AP donation. Delayed VVRs were only recorded in donors of age ≤24 years ($P = .008$).

Two of the donor complained of delayed muscular spasms/ leg cramps. Both the donors also had an episode of leg cramps during the plateletpheresis procedures. One donor had a weight of 66 kg and procedure required 421 mL ACD and another was 60 kg and required 464 mL of ACD during the plateletpheresis procedure. Both the spasm episodes were reported within 6 hours of donation and did not have any long term consequences.

### 4.3 | Independent observations

Three donors reported having a fever after AP procedure. The fever episodes were reported between day one and day nine of donation. In all the cases the fever receded without any diagnosis and complications. Diarrhea was reported by a single donor on day four of donation. None of the donors required hospitalization.

## 5 | DISCUSSION

Delayed adverse events in AP donations are unexplored territory, as the BTS do not usually follow-up donors once they leave the donor premises. This study highlights that majority of ADEs in the form of D-ADEs go unreported. D-ADEs were four times more common than I-ADEs (19.21% vs 5.46%). The profile of D-ADEs is different from I-ADEs. Hematomas and muscular spasms were the most common I-ADEs whereas bruising and sore arms were the most common D-ADEs. Bruising is a stage in the healing of hematomas, and sometimes may be accompanied by soreness in the arm. This, in turn, gives an overall higher incidence of D-ADEs.

### 5.1 | Immediate adverse donor events

In the present study, the incidence of paresthesiae was 51.6%. This incidence is higher as compared to that reported in previous studies.[3-8] Many times the donor may confuse paresthesiae with the vibrations from the centrifuge of the apheresis equipment. Hence, the actual incidence of citrate effect may be lower than perceived.

An active inquiry of symptoms may determine the exact magnitude of citrate toxicity. Makar et al reported the incidence of mild citrate toxicity to be 25.97% and 2.78% when donors were specifically asked and not asked about the symptoms respectively.[3] Low body weight (≤75 kg) and moderate to low platelet counts ($\leq 230 \times 10^3/\mu L$, which invariably leads to longer procedure times and higher ACD requirements), are the two most important predictors of citrate toxicity.

Mild circumoral/digital paresthesiae are very common with AP donations and authors recommend that these ADEs may be called citrate effect and the term citrate toxicity should be reserved for spasm/tetany or severe paresthesiae requiring discontinuation or stoppage of the AP procedures.

Incidence of immediate hematoma (3.58%) was comparable (0.08%-7.4%) to other apheresis studies.[4,6-8] Majority of the hematomas (68.42%) were recorded during the return cycle of apheresis. Hence it is very important to be vigilant at the start of the first return cycle so that the extent of hematoma can be minimized. Incidence of spasms was higher as compared to the study Mcleod et al (1.13% vs 0.05%). The higher incidence may be related to the prospective nature of the present study. Incidence of VVRs was comparable to other studies (0.1%-0.85%).

### 5.2 | Delayed adverse donor events

#### 5.2.1 | Localized delayed adverse donor events

Localized D-ADEs were more common than systemic D-ADEs (16.01% vs 3.20%, $P < .001$). Sports activities, strenuous physical activity, lifting of bags/ luggage or re-trauma to the phlebotomy site may be few of the reasons for delayed hematomas. There was no co-relation between hematoma formation and any donor parameters. This may be because the veins of AP donors are carefully checked and only prospective donors with adequate veins are considered eligible for plateletpheresis.

Allergic events, sore arms, and post-donation weakness or fatigue are few of the other D-ADEs, which are usually not encountered during and post-donation period in the blood donation premises. Approximately 2 % of the donors

reported allergic events at the site of phlebotomy. Sensitivity to medicated adhesive bands or antiseptics used for disinfection or metal alloy of the needle may be the causes for the delayed allergic reaction in blood donors.[10] Bruising was also (7.34%) common as hematomas later on present as bruises and sometimes minute amounts of blood may seep into the subcutaneous tissue which may not be sufficient to cause a hematoma but sufficient to present as bruising. No cases of nerve injury were detected in our study. The reason for this may be nerve injury may get disguised in sore arms or paresthesia category.

### 5.2.2 | Systemic delayed adverse donor events

Delayed VVRs can occur up to 24 hours. Though VVRs are usually mild, the donor is at risk of sustaining injuries due to fall or they may have serious implications if the donor is doing work requiring continuous attention like driving or working on machinery.

The incidence of post-donation weakness or fatigue was more common in first-time donors (5.70% vs 0.80%, $P < .001$). The possible reasons can be as first-time donors may not follow post-donation advice meticulously and they are usually more anxious.

Post donation muscular spasm was reported in two donors. Both these donors also had intra-procedure muscular spasms. Weight of the donor and ACD required for the procedure are the important predictor for delayed the muscular spasms. A study by Bolan and collegues[11] has shown the benefit of giving high doses (2 g) of prophylactic oral calcium, though a recent meta-analysis[12] suggests no significant co-relation between prophylactic oral calcium supplements and prevention of citrate toxicity. Blood donors with low body weight (≤75 kg) and moderate platelet counts ($\leq 230 \times 10^3/\mu L$) (usually require a higher volume of ACD for the procedure) may be given prophylactic oral calcium tablet to decrease the citrate toxicity.

All the I-ADEs were grade I and all the D-ADEs were grade II as per the grading severity of blood donor adverse events tool by AABB donor haemovigilance working group.[13]

### 5.2.3 | Significance of active donor follow-up

Routinely very few donors revert to the BTS in case of any D-ADEs. Sometimes AP donors may call or visit BTS for their apprehensions regarding D-ADEs. But this information does not give the correct magnitude of D-ADEs in the donor population. All BTSs have a system for documenting and reporting of any I-ADEs but do not have any similar system regarding D-ADEs. The only sources of information regarding D-ADEs for BTS are passive information provided by the blood donors. A study of this nature emphasizes the importance of D-ADEs in AP donors. AP donors are a special pool of altruistic donors and proper care, advice and follow-up may go a long way in retaining these donors.

### 5.3 | Strengths of the study

The present study is the first study which gives insight into D-ADEs in AP donors. Donors were contacted twice that is, after 24 hours and after 14 days of AP donation for all the D-ADEs. Many times donors may have forgotten acute adverse events if contacted late. In the present study, all the telephonic interviews were made by a Medical Resident in order to obtain correct information regarding ADEs.

### 5.4 | Limitations of the study

Although no leading questions were asked, subjective bias with regard to symptoms may be present on active questioning. Many times the donor may exaggerate symptoms when specifically asked. Sometimes donors are reluctant to report any events as it goes against their perceived notion of being in good health. The identification of D-ADEs was based on the subjective interpretation of the blood donor rather than objective assessment by medical personnel. This may have caused false under-reporting or over-reporting of certain D-ADEs like fatigue, allergy, etc. Due to socio-cultural reasons, majority of our platelet donors are males and very few females come forward for platelet donations though they donate blood. In the study period, no female donor donated platelets and all AP donors were males; hence gender-wise comparison was not possible.

## 6 | CONCLUSIONS

AP donations are relatively safer procedures without any long term consequences. D-ADEs are more common than I-ADEs. Localized ADEs in form of bruise and hematomas are more frequent than systemic ADEs like fatigue and VVRs. First-time donors are more prone to ADEs than repeat donors.

## 7 | RECOMMENDATIONS: MEASURES TO PREVENT D-ADEs

BTS staff usually does not have exposure to D-ADEs and may not be able to give proper advice, if a donor calls or comes back to the BTS with a query regarding D-ADEs. BTS staff should be trained to manage and advise regarding D-ADEs and refer them to the BTS doctor where needed.

BTS needs to re-emphasize following during post donation counseling: (1) Advice regarding fluid and electrolyte intake on the day of donation. (2) Special care of the

phlebotomy site. (3) No heavy weight lifting or strenuous exercise on the day of donation. (4) In case of soreness of arm: application of ice. (5) Information to BTS regarding any delayed ADEs.

VVRs may occur up to 24 hours after AP donation but the majority of VVRs occur during the first 6 hours. Though most of the delayed VVRs are mild, significant injury can occur to the donor or a nearby person in case of any work requiring continuous attention. Medicated adhesive bands and povidone iodine should be avoided in donors with a history of allergy to topical antibiotics and iodine respectively. Sports activities, strenuous physical activity, lifting of bags/luggage or re-trauma to the phlebotomy site may be few of the reasons for the delayed hematomas. Post donation counseling to avoid these activities may be an important measure to prevent delayed hematoma formation.

Special care should be taken in low weight donors and donors with low platelet counts as donor weight and platelet count are the most important predictors of immediate and delayed systemic ADEs. Donors at risk for hypocalcemia may be given prophylactic oral calcium tablets prior to the procedure along with pre-donation counseling regarding symptoms of citrate effect and toxicity.

Majority of D-ADEs were elicited during the 24 hour follow up call and 2 week follow up call was more relevant for identifying bruises and continued sore arms. We recommend that 24 hour follow up call is more relevant as donors may forget minor ADEs if contacted late.

## CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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