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Original Research Article

Profile of adverse events in plateletpheresis and plasmapheresis donors in a tertiary care hospital of North India

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ABSTRACT

Background: Apheresis procedures are usually well tolerated. Adverse events (AEs) associated with the use of cell separators can be due to delivery of the anticoagulant, vasovagal, allergy, venous access or machines malfunction. Aim was to study the profile of adverse events of plateletpheresis and plasmapheresis donors.
Methods: Plateletpheresis and plasmapheresis procedures enrolled for donors during 2017-2018 were done after taking informed and written consent by using Trima Accel and MCS+cell separator. Donor related AEs were categorised according to severity, site and etiology. Non-donor related (NDR) AEs were kit, technique, or equipment related.
Results: 2859 procedures were done, 2836 (99.19%) plateletpheresis and 23 (0.8%) plasmapheresis. All 145 (5.07%) AEs were seen in plateletpheresis. Majority of AEs, 130 (4.54%) were DR. 15 (0.52%) were NDR. Commonest DR AEs was citrate related (CR) 76 (2.6%), followed by vasovagal reaction (VVR) in 31 (1.08%) and vascular injury in 23 (0.8%). Majority of the AEs were mild in 124 (4.33%), only 6 (0.20%) were moderate. 107 (3.74%) AEs were (VI) systemic, while 23 (0.80%) were local. In local AEs, hematomas were more common. First time donors had more AEs, 62/1234 (5.02%) as compared to the repeat donors 68/1625 (4.18%). CR AEs were more in repeat donors, 46 (2.8%) as compared to first time donors, 30 (2.43%). VVRs and VIs were more in first time as compared to the repeat donors. NDR AEs were 15 (0.52%).
Conclusions: Donor vigilance, trained technical personnel and specialists' supervision are vital for donor safety hence affecting apheresis donor pool.

Key words: Apheresis donor, Donor related adverse events, Non donor related adverse events, Citrate reactions,

INTRODUCTION

In apheresis collections, blood components of standardized volumes and predictable doses can be collected despite variations in donor characteristics. Apheresis procedures are usually well tolerated. Adverse Events (AEs) associated with the use of cell separators can be due to delivery of the anticoagulant, vasovagal, allergy, venous access or machines malfunction. The overall rate of AEs with apheresis donation is approximately 10 times less than that seen with whole blood (WB) donation, with mild events outnumbering the more severe ones, although the frequency of events requiring hospitalization may be higher in apheresis than with WB donation.[1] Hospitalization is still extremely rare; it occurred in 0.01% of donations in one study.[2]

Aim and objectives

Aim and objective of the study was to study the profile of AEs associated with plateletpheresis and plasma-pheresis in a tertiary care hospital of North India.

METHODS

Setting design

Current study is a prospective, cross-sectional, open label study.

Procedure

A total of 2859 plateletpheresis and plasmapheresis procedures enrolled for donors during 2017-2018 were done after taking informed and written consent by using Trima Accel and MCS+cell separator. Trima Accel (TA) (Terumo BCT, Lakewood USA), a continuous type of cell separator and MCS+(Haemonetics Corp., Braintree, USA) an intermittent type of cell separator were used. Ethical clearance was taken from the institutional ethical committee. All the donors were selected according to the guidelines laid down by Director General Health Services.[3] AEs occurring during or after the apheresis procedure were noted by nursing/technical staff under the supervision of a transfusion medicine specialist, to eliminate observer bias. AEs were divided according to type: donor related (DR) and non-donor related (NDR).[4] DR AEs were categorised according to severity of AE (e.g. mild, moderate, or severe), according to site (local and systemic), according to etiology (hypotensive reactions, citrate related (CR) AEs, hematomas and infiltrations, loss of consciousness and seizures, allergy).[5,6] Local reactions were usually haematomas due to extravasation from the veins, caused by incorrect placement of the needle during the venipuncture. Pain, hyperaemia and swelling may develop at the site of the extravasation. Local phlebitis and thrombophlebitis are very rare.[7] Systemic reactions were mainly associated with vasovagal reactions (VVR) that can be triggered by the pain of the venipuncture, or by anxiety. These were characterized by the pallor, sweating, dizziness, nausea, hypotension, bradycardia, and syncope. Citrate toxicity occured because of the use of acid-citrate-dextrose (ACD) in apheresis.[7] NDR AEs were categorized as equipment/kit/technique related. Equipment related problems can be multiple like air purge failures, variation in the anticoagulant (AC) ratio, changes in calibration of equipment etc.[8] Kit/technique related AEs were secondary to improper disposable sets /improper mounting of the set (technique related). These were haemolysis, thrombus formation, air embolism, leakage, infection etc.[5] Data was compiled in a Microsoft Excel spread sheet and presented as a mean±standard deviation, numbers and percentage according to requirement. Results were analyzed using Chi-square test (χ test). Statistical analysis was conducted using the SPSS (version 17) for Windows statistical package.

RESULTS

A total of 2859 procedures were done, 2836 (99.19%) plateletpheresis and 23 (0.8%) plasmapheresis. Out of the plateletpheresis procedures done, 666 (23.48%) procedures were done on TA while 2170 (76.51%) were done on MCS+. All 23 (100%) plasmapheresis procedures were done on MCS+.

Apheresis donor profile

Maximum apheresis donors 1452 (50.78%) were in the age group of 21-30 yrs, the mean age was 30.74 yrs±8.44 SD with a range from 18 yrs to 65 yrs (Figure 1).

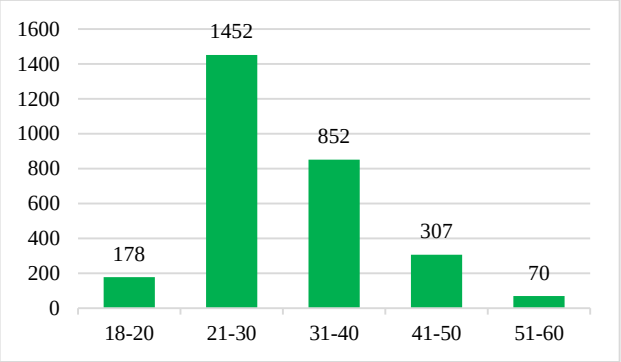

Figure 1: Age wise distribution of overall apheresis donors.

Maximum donors, 1190 (41.62%) were in the 60-70 kg category. The mean weight of the donors was 74.33 kg ±9.80 SD with a range from 60 kg to 100 kg. The mean height of the donors was 170.46 cm ±4.99 SD with a range from 154 cm to 182 cm. There were only 4 (0.15%) female plateletpheresis donors. All the 23 (100%) plasmapheresis donors were males (Table 1). Majority of apheresis donors were voluntary, 2023 (70.76%), while 836 (29.24%) were replacement donors. Repeat donors 1625 (56.81%) were dominating the first time donors 1234 (43.16%). The mean predonation platelet count was 272.98±56.59×10^9/l with maximum donors having platelet count between 200 to 300×10^9/l. Mean predonation Hb of apheresis donors was 14.87 gm% ±3.16 SD. The mean predonation TSP was 6.31 g/dl ±4.8 SD with a range from 6 to 7.6 g/dl.

Adverse event profile

All 145 (5.07%) AEs were seen in plateletpheresis, none was encountered in plasmapheresis. Majority of AEs, 130 (4.54%) were related to donors. Very few, 15 (0.52%) were NDR. AEs associated with apheresis procedures on TA and MCS+ are shown in (Table 2). The frequency distribution of DR AEs was 130 (89.65%) and NDR was 15 (10.34%). Frequency of CR AEs in 76 (52.41%) donors, followed by VVR in 31 (21.37%) and VI in 23 (15.86%) donors. Frequency of AEs during apheresis on TA and MCS+ are shown in (Table 3). Frequency distribution of NDR AEs were 15 (10.34%) with faulty technique in 6 (4.13%) cases followed by faulty kit in 5 (3.44%) and equipment related in 4 (2.75%) procedures. The frequency of NDR AEs on TA and MCS+ are shown in (Table 4).

Table 1: Sex wise distribution of apheresis donors.

Sex	Plateletpheresis N (%)	Plasmapheresis N (%)	Overall apheresis N (%)
Male	2832 (99.85)	23 (100)	2855 (99.86)
Female	4 (0.15)	--	4 (0.139)

Table 2: Incidence of AEs associated with apheresis.

Type of AEs	AEs on TA N (%)	AEs on MCS+ N (%)	Total AEs with apheresis N (%)
Donor related	32 (4.8)	98 (4.5)	130 (4.54)
Non donor related	5 (0.75)	10 (0.46)	15 (0.52)
Total	37 (5.5)	108 (4.9)	145 (5.07)

Table 3: Frequency distribution of donor related AEs associated with apheresis.

Type of DR AEs	DR AEs on TA N (%)	DR AEs on MCS+ N (%)	Total DR AEs N (%)
Citrate related	15 (10.34)	61 (42.06)	76 (52.41)
Vasovagal reaction	10 (6.89)	21 (14.48)	31 (21.37)
Vascular injury	7 (4.89)	16 (11.034)	23 (15.86)
Total	32 (22.06)	98 (67.58)	130 (89.65)

Table 4: Frequency distribution of non-donor related AEs associated with apheresis.

Type of NDR AEs	NDR AEs on TA N (%)	NDR AEs on MCS+ N (%)	Total NDR AEs N (%)
Equipment related	1 (0.689)	3 (2.06)	4 (2.75)
Kit related	1 (0.689)	4 (2.758)	5 (3.44)
Technique related	3 (2.06)	3 (2.068)	6 (4.13)
Total	5 (3.44)	10 (6.89)	15 (10.34)

Donor related AEs during apheresis procedures

The incidence of DR AEs showed that the most common DR AE was CR, seen in 76 (2.6%) donors followed by VVR, 31 (1.08%) and vascular injury (VI) 23 (0.8%) donors. Incidence of DR AEs associated with apheresis procedures on TA and MCS+ in are shown in (Table 5). The majority of the AEs were mild in nature, 124 (4.33%), 6 (0.20%) donors had moderate reaction, no severe reaction was recorded. All the AEs were managed in the donor room and none of it needed referral to the hospital. Majority of the AEs 107 (3.74%) were systemic, while only 23 (0.80%) were local. In VVRs, 25 (0.87%) developed nausea, vomiting and pallor while 6 (0.20%) donors had loss of consciousness for <1 minutes along with mild symptoms. In CR AEs out of 76 (2.6%) donors, 52 (01.8%) donors developed numbness and tingling, while 24 (0.8%) donors developed perioral paraesthesias. The local AEs in apheresis procedures were VI which included hematomas and bruise. No case of nerve injury was seen. Amongst the VI, hematomas 14 (0.49%) were more than bruise 9 (0.31%). The first-time donors had more AEs, 62 (5.02%) as compared to the repeat donors having AEs in 68 (4.18%). CR AEs were more in repeat donors, 46 (2.8%) as compared to first time donors, 30 (2.43%). The VVRs and VI were more in first time donors, as compared to the repeat donors, 18 (1.48%) and13 (0.8%), 14 (1.1%) and 9 (0.55%) respectively (Figure 2).

Non donor related AEs during apheresis procedures

Incidence of NDR AEs 15 (0.52%) showed technique related AEs in 6 (0.2%) followed by kit related in 5 (0.17%) and equipment related as 4 (0.139%) procedures. Kit problems were mainly secondary to the improper disposable sets. Technique related AEs were due to improper mounting of the kit on the machine. Inexperienced technical support had encountered this problem. The incidence of NDR AEs on TA and MCS+ are shown in (Table 6).

Causes of NDR AEs in TA

Causes are; equipment related AE was due to air purge failure in one case (0.15%), Kit related AE was due to kit leakage in one case (0.15%) and Technique related AE were seen in 3 (0.45%) cases, due to ACD being connected early in one case; donor line clamp not being

opened on time in one case and improper fitting of separation chamber on rotator cup in one case.

Table 5: Incidence of donor related AEs associated with apheresis.

Type of DR AEs	DR AEs on TA N (%)	DR AEs on MCS+ N (%)	Total DR AEs N (%)
Citrate related	15 (2.2)	61 (2.7)	76 (2.6)
Vasovagal	10 (1.5)	21 (0.95)	31 (1.08)
Vascular injury	7 (1.05)	16 (0.72)	23 (0.8)
Total	32 (4.8)	98 (4.5)	130 (4.54)

Table 6: Incidence of non-donor related AEs associated with apheresis.

Type of NDR AEs	NDR AEs on TA N (%)	NDR AEs on MCS+ N (%)	Total NDR AEs N (%)
Equipment related	1 (0.15)	3 (0.138)	4 (0.139)
Kit related	1 (0.15)	4 (0.184)	5 (0.17)
Technique related	3 (0.45)	3 (0.138)	6 (0.2)
Total	5 (0.75)	10 (0.46)	15 (0.52)

Causes of NDR AEs in MCS+

Causes are; equipment related AE in 3 (0.138%) cases were due to air purge failure; bowl related problem and change in calibration of equipment in one case each, Kit related AE in 4 (0.184%) cases were due to kit leakage due to breakage of separation chamber in two cases; excessive kinks in the tube were present in one case and RBC spillage in one case and Technique related AE in 3 (0.138%) procedures was due to wrong selection of program modules.

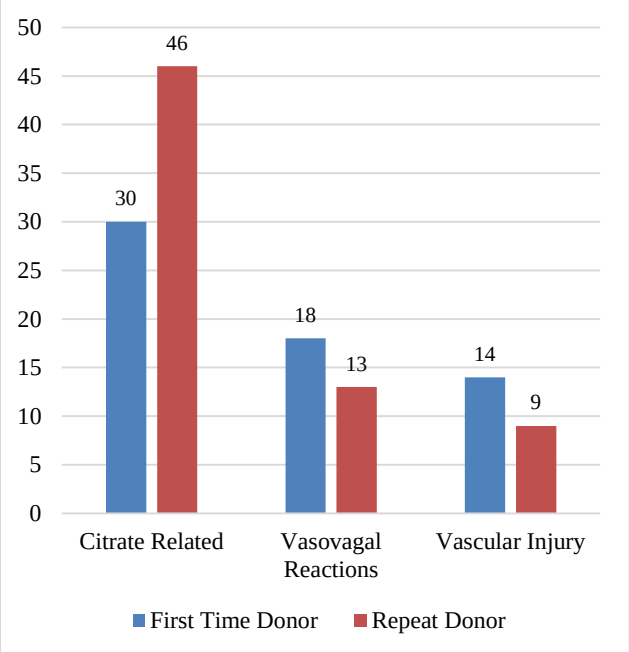

Figure 2: Donor related AEs in first time and repeat apheresis donors.

DISCUSSION

Apheresis donor profile

The potential apheresis donor should meet several requirements to be accepted as a suitable candidate for blood component donation.[8] Criteria such as hematocrit or haemoglobin levels, age, weight and minimum platelet count are important for the safety of the donor.[9] Weight or body mass is indicated as criterion to maximize plateletpheresis donation because higher platelet yields can be obtained from larger donors with higher blood volume.[10] Age and weight wise distribution donors in the present study is similar to literature.[11,12] In present study, most of the apheresis donors 2855 (99.86%) were male. Only 4 (0.139%) donors were female. Several studies show a similar profile for donation, in which there were larger number of male donors.[10,13,14] In the present study, maximum apheresis donors, were voluntary and repeat. It may be due to the fact that voluntary donors were repeat donors.

Adverse event profile

Although apheresis procedures are considered to be safe, data reported in the medical literature about the frequency of adverse events during donations show a broad heterogeneity. Literature suggests that apheresis procedures are well tolerated and donors experience AEs at rates similar to or even lower than those seen with WB donations. It is likely due to the more modest fluid shift and smaller net fluid deficit associated with apheresis procedures.[1] In the present study no female donor experienced adverse event which is similar to Dogra et al which may be a chance occurrence only.[15] Yuan et al reported that females were approximately 2.5 times more

likely to have an AE of any type compared to male donors.[13]

Table 7: Comparison of frequency distribution of AEs in apheresis in various studies.

Name of the study	Donor related AEs (%)	Equipment/Kit related (%)	Technique related (%)
Patidar et al[4]	95.6	4.4	-
Dogra et al[15]	78.43	14.71	6.86
Bassi et al[11]	61.53	23.07	15.38
Present study	89.65	6.21	4.14

Table 8: Comparison of incidence of donor related AEs in various studies.

Name of the study	Citrate related AEs (%)	Vasovagal reactions (%)	Vascular injuries (%)	Overall donor related AEs (%)
Crocco et al[17]	0.38	0.24	-	0.62
Philip et al[8]	0.96	0.09	1.6	2.72
Patidar et al[4]	9	0.8	7.4	17.2
Sujatha et al[18]	0.91	0.39	1.56	2.86
Dogra et al[15]	2.7	0.76	1.2	4.66
Khajuria et al[19]	3.03	1.51	1.51	6.06
Bassi et al[11]	1.4	0.9	1.3	3.75
Present study	2.6	1.08	0.8	4.54

Tomita et al reported a higher incidence rate of AEs in female apheresis donors.[14] Comparison of incidence of AEs in apheresis in various studies showed that the incidence of AEs in the present study were 5.07%. This was comparable to the literature whereas Patidar et al reported a significantly higher incidence of AEs.[4,11,12,15] Comparison of frequency of AEs in apheresis in various studies showed that in the present study majority of the AEs were donor related, 89.65% with kit/equipment related and technique related AEs was 6.21% and 4.14% respectively. Patidar et al and Dogra et al reported similar trend while Bassi et al showed higher kit/equipment and technique related AEs (Table 7).[4,11,15] First time donors have more AEs than repeat donors in the present study as reported in literature.[2,12,16] Patidar et al reported contrary to the above results.[4] The present study showed that CR AEs were more in repeat donors while the VVRs and VIs were more in the first time donors which was also recorded by Patidar et al.[4] The present study showed that predominant AEs were mild, 4.33% which was also endorsed by the literature.[12,17,18] Moderate AEs were few with 0.20% donors experiencing AEs which was also observed in literature.[4] No severe AE was seen in the present study. The literature also showed that severe AE are rare as reported by Crocco et al as 0.004%.[17]

Donor related AEs associated with apheresis

Citrate-related AEs: The incidence of DR AEs in the present study showed that the CR AEs was 2.6%, which was in accordance with the literature.[15,19] Patidar et al reported a very high CR AEs, 9%.[4] While other studies reported a low CR AEs rate (Table 8).[8,11,17,18] Variation in CR AEs may be attributed to administration of oral calcium tablets to the donors at the beginning of the procedures, difference in the donor characteristics, duration of the procedures and equipment's used. In the present study the plateletpheresis session profile of reactors (citrate toxicity) and non-reactors showed that amount of ACD used and WB processed in reactors was more, as compared to non-reactors and was similar to study done by Patidar et al.[4]

Literature showed that donors who undergo the procedure repeatedly or for prolonged periods are susceptible to an accumulation of citrate, as levels exceed the amount that can be metabolized by the body.[9] While we did not determine preprocedural ionized calcium level in the present study Bolan et al.[20] found an average fall in ionized calcium of 33% from baseline which produces the signs and symptoms of citrate toxicity. The results of administration of oral calcium carbonate and its effects on citrate toxicity by Bolan et al reported that the administration of 2 g of calcium carbonate was associated with a statistically significant reduction in the severity of paraesthesias.[20] Philip et al gave calcium supplementation in the form of 1gm capsules of calcium carbonate orally.[8] The treatment of citrate reactions includes slowing the re-infusion rate, increasing donor blood-to-citrate ratio, oral calcium supplementation, and if required, giving intravenous calcium.[7]

Vasovagal reactions

The VVRs in the present study was 1.08% which was close to other studies while some reported less number of VVR (Table 8).[4,8,11,15-19] Systemic reactions were mainly VVRs, triggered by either the anxiety related to apheresis procedure or the apprehension of needle-prick.[8] Bueno et al stated the rate of presyncopal (PS) seen with procedures performed on TA was four times higher than

those performed on Amicus instruments, with the distinction being that only the latter instrument routinely provided donors with saline replacement.[21] Yuan et al stated different types of AEs seen in apheresis donors may have different sets of risk factors.[13] Although most donors can tolerate the procedures well without supplemental fluid replacement, PS in high-risk donors may be prevented by providing supplemental saline infusion as an extra measure of donor safety.[13]

Vascular injuries

Significant VIs are post donation hematomas or nerve injuries, because such injuries can induce significant donor discomfort and may require a prolonged recovery period.[22] VIs may also adversely affect donor satisfaction as well as retention.[23] VIs in the present study were 0.8% which was close to literature.[8,11,15,18,19] While Patidar et al[4] reported a very high rate of VI (Table 8). These often present as haematomas. These are usually due to faulty phlebotomy technique by in-experienced technical staff leading to extravasation of blood, the number of prior apheresis donations, and the anatomy at the venepuncture site. Yuan et al reported that smaller donor total blood volume (TBV), female sex, and possibly younger age were associated with a greater likelihood of postdonation hematomas.[13] The latter association is likely because donors with smaller body size, who are often female or younger, tend to have smaller veins. Thus, they are more prone to VI when access needles of the same gauge are used for all donors. Unlike citrate reactions, which are more likely to occur in repeat donors, the probability of bruising reduces with the number of donations.[24] Literature supports that only women were associated with complications related to venipuncture.[9] In the present study no female apheresis donor had any AE.

Non-donor related AEs during apheresis procedures

NDR AEs 15 (0.52%) relating to equipment/kit/technique showed technique related AEs as 6 (0.2%) followed by kit related, 5 (0.17%) and equipment related as 4 (0.139%) procedures. In study conducted by Dogra et al equipment related problems comprised 15 (14.71%) events those included 4 (3.93%) air purge failures (2 in MCS+ and 1 each in COMTEC and TA), 3 (2.94%) defective kits (leakage from separation chamber in 2 kits for COMTEC and in 1 kit for MCS+) and 8 (7.84%) high/low AC ratio (in MCS+ leading to disabling the ACD drip monitor).[15] Technical aberrations included 7 (6.86%) events which included 2 (1.96%) wrong selections of programme modules (COMTEC), 3 (2.94%) events due to ACD being connected early (TA) and 2 (1.96%) events due to the donor line clamp not being opened on time (TA). Bassi et al reported that 0.938% events were technique related due to low inlet pressure, donor line clamp was not opened on time and (1.40%) were due to defective kits. Equipment related problems can be multiple like air purge failures, variation in the AC ratio, changes in calibration of equipment.[8,11]

Limitations

Limitation of current study was due to small number of plasmapheresis donors, the prevalence of AEs of plasmapheresis was not known.

CONCLUSION

AEs associated with apheresis can be reduced by meticulous donor vigilance, trained technical personnel under the supervision of transfusion medicine specialists, preventive maintenance by the system engineers, proper inspection of the defective kits at the manufacturing site and before installation will affect the voluntary apheresis donor pool.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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