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Original Research

Assessment of adverse events associated with apheresis procedures

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***ABSTRACT*:**
Background: Over decades, increased demand of platelet transfusions for patients with various medical and surgical diagnoses led to accelerated usage of technologically advanced "Apheresis" for platelet concentrates which is conducted under the transfusion medicine specialist's supervision in special dedicated areas. Hence; the present study was conducted with the aim of assessing adverse events associated with apheresis procedures. **Materials & methods:** A total of 500 apheresis procedures were analysed in the present study. Complete demographic details of all the patients were obtained. A Performa was designed and complete details were recorded in it. All adverse events were recorded by the staff. The adverse events occurring during or after the procedures were classified as vascular injuries (VIs), citrate reaction (CR), presyncopal/syncopal (PS/S), and PS + CR both. All the results were recorded and analysed using SPSS software. **Results:** Overall, vascular injuries were seen in 4 patients while citrate reaction was seen in 3 patients. Among vascular injuries, 2 adverse reactions were seen during procedure while the remaining 2 cases were seen after procedure. **Conclusion:** Apheresis donations have very less fraction of acute reaction rates which are relatively mild and easily treated.
Key words: Adverse events, Apheresis

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INTRODUCTION

Over decades, increased demand of platelet transfusions for patients with various medical and surgical diagnoses led to accelerated usage of technologically advanced "Apheresis" for platelet concentrates which is conducted under the transfusion medicine specialist's supervision in special dedicated areas. In apheresis, whole blood is drawn from healthy donors, processed in specialized equipments viz. the automated cell separators which facilitate in-line separation of cellular from plasma component and then, selective extraction of required component with the 'depleted blood' being returned back to the donors. Many authors have reported the apheresis as a safer procedure which is associated with less frequent adverse donor reactions as compared to whole blood donations.[1- 3] There are reports in the literature that suggest that apheresis procedures are well tolerated and that donors experience adverse events (AEs) at rates similar to or even lower than those seen with whole blood (WB) donations, likely due to the more modest fluid shift and smaller net fluid deficit associated with apheresis procedures.[4- 6] Hence; the present study was conducted with the aim of assessing adverse events associated with apheresis procedures.

MATERIALS & METHODS

The present study was conducted with the aim of assessing adverse events associated with apheresis procedures. A total of 500 apheresis procedures were analysed in the present study. Complete demographic details of all the patients were obtained. A Performa was designed and

complete details were recorded in it. Exclusion criteria included:

- Patients with body weight of less than 50 kg,
- Patients above 60 years of age
- Patients less than 18 years of age

All adverse events were recorded by the staff. The adverse events occurring during or after the procedures were classified as vascular injuries (VIs), citrate reaction (CR), presyncopal/syncopal (PS/S), and PS + CR both. All the results were recorded and analysed using SPSS software. Chi-square test was used for evaluation of level of significance.

RESULTS

A total of 500 apheresis procedures were analysed in the present study. Overall, vascular injuries were seen in 4 patients while citrate reaction was seen in 3 patients. Among vascular injuries, 2 adverse reactions were seen during procedure while the remaining 2 cases were seen after procedure.

Table 1: Adverse events

Adverse events		Plateletpheresis procedures
Vascular injuries	During procedure	2
	After procedure	2
Citrate reaction	Mild to moderate	1
	Severe – Tetany	1
	Presyncopal/syncopal	1
	PS + CR	0

DISCUSSION

Although apheresis and blood donation are generally considered to be safe procedures, the incidence of adverse effects in donors has not been determined in large, multicentre series of donations. Moreover, data are lacking on the incidence of adverse effects of donations made with modern apheresis instruments.[6- 9] Hence; the present study was conducted with the aim of assessing adverse events associated with apheresis procedures.

A total of 500 apheresis procedures were analysed in the present study. Overall, vascular injuries were seen in 4 patients while citrate reaction was seen in 3 patients. Among vascular injuries, 2 adverse reactions were seen during procedure while the remaining 2 cases were seen after procedure. Joseph Philip et al analyzed a total of 3,367 apheresis procedures, out of which 3,120 were plateletpheresis procedures, and out of which 1,401 were on Baxter CS 3000 & 1,719 were on Haemonetics MCS+ cell separators. Rest of 247 TPE & PBSC procedures were done on Haemonetics MCS+ cell separators. 90 AEs were reported in relation to the 3,367 procedures. Out of 90 AEs, 85 AEs (94%) were associated with plateletpheresis (n = 3,120) and 05 AEs (06%) with TPE & PBSC (n = 247). The rate of vascular injury (VI), Citrate reaction (CR), and Presyncopal/Syncopal (PS/S) in plateletpheresis was 1.6% (52/3,120), 0.96% (30/3,120), and 0.096% (03/3,120), respectively. The rate of CR in TPE and PBSC was 1.23% (02/162) and 2.3% (02/85), respectively. The rate of PS/S in PBSC was 1.17% (01/85). AEs for Plateletpheresis, TPE & PBSC were 2.7% (85/3,120), 1.23% (02/162), and 3.5% (03/85), respectively. VI, CR, and PS/S were mostly of mild intensity. Both cell separators were equally safe, when AEs associated with plateletpheresis were compared with each other; 2.8% on CS 3000 & 2.6% on MCS+. Apheresis procedures performed on cell separators are safe, with a low incidence of significant AEs.[10]

Dogra K et al evaluated the incidence of such adverse events associated with the modern apheresis procedures that would provide an insight as well as help formulating preventive steps to avoid frequent occurrences of such events. This prospective audit-based observational study was conducted over 1 year. Donors for plateletpheresis were selected as per the standard operating procedure of the Apheresis Lab. The apheresis procedures were done on the MCS+ (Haemonetics Corp.), Trima Accel (Terumo BCT) and COM.TEC (Fresenius Kabi AG). 1740 apheresis procedures were performed, out of which 1708 were plateletpheresis and 32 therapeutic plasma exchange (TPE) procedures for 7 patients. A total of 102 adverse events were noted; of which, 80 (78.43 %) events were associated with donors, 15 (14.71 %) were owed to equipment related problems and 7 (6.86 %) were technical aberrations. All the events associated with donors were mild. No adverse events were reported with any of the 32 TPEs. Apheresis procedures are associated with adverse events which can be reduced by meticulous donor-vigilance, superior training modules for the technical personnel and continued supervision of experienced transfusion medicine specialists.[11] Crocco I et al recorded a total of 686 adverse reactions (related to 0.28% of all donations). Vasovagal reactions, mostly of mild intensity, were the most commonly observed adverse reactions, with a frequency of 0.20% (487/ 240,596). The frequency of the vasovagal reactions varied according to the different types of donation, being 0.19% (346/183,855) for homologous whole blood donations, 0.24% (16/6,669) for autologous whole blood donations, 0.16% (63/38,647) for plasmapheresis, 0.68% (18/2,641) for plateletpheresis and 0.49 (43/8,784) for multicomponent donations. Citrate toxicity was reported in 0.38% (189/50,072) of apheresis donations. Severe adverse reactions were very rare, as they occurred in 0.004% of the donations (10/240,596). In conclusion, the results of our 5-year survey document that apheresis and blood donation are safe procedures for the donor with a low incidence of adverse reactions; the adverse reactions that did occur were mostly mild and resolved rapidly.[12]

CONCLUSION

Apheresis donations have very less fraction of acute reaction rates which are relatively mild and easily treated.

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