Original Article

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Adverse Events Associated with Plateletpheresis: A Tertiary Care Hospital Experience in Southern India

Transfusion Medicine Section

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ABSTRACT

Introduction: Platelet transfusions play a major role in preventing major haemorrhage and improve survival in severe thrombocytopenic patients. Generally, apheresis procedures are well tolerated. Systemic reactions are mainly vasovagal reactions and citrate toxicity is also one of the common reaction.

Aim: To identify the profile of platelet donors associated with adverse events resulting from plateletpheresis donation.

Materials and Methods: This retrospective study was carried out for a period of three years. A total of 615 Single Donor Platelet (SDP) apheresis procedures were performed during study period. Both continuous and intermittent flow centrifugation cell separators (Fresenius Kabi and Trima Accel) were used for performing the procedures. Predonation donor platelet count and other procedure variables were analysed in relation to the adverse events noted using the Pearson correlation.

Results: Age range of SDP varied from 19 years to 48 years. Platelet counts of the donors ranged from 1.6 to 4.5 lac/dL. Amongst the selected 615 donors, 15 (2.43%) had citrate related toxicity reactions, 2 (0.32%) had a vasovagal reactions, 8 (1.3%) had mild haematomas. Increase in the amount of Acid Citrate Dextrose (ACD) volume used (r=0.99, p-value <0.005), was associated with increased duration of the procedure and low donor platelet count. Among the donors who suffered adverse events, 22 (88%) were first-time platelet donors and 3 (12%) were repeat donors.

Conclusion: The overall rate of acute adverse events, among healthy SDP in our study was very low. However, in the study citrate toxicity increased in donors with platelet count <2.5 lac/dL. Precautions and close monitoring in such cases helps in decreasing the severity of citrate toxicity.

Keywords: Adverse events, Citrate toxicity, Single donor platelet

INTRODUCTION

Platelet transfusions play a major role in preventing major haemorrhage and improve survival in severe thrombocytopenic patients [1]. Platelet units obtained by plateletpheresis are called SDP. The number of platelets in an apheresis product is equivalent to 6-10 random platelet concentrates and contains at least 3.0×10^{11} platelets [2]. Now-a-days, there is an increased demand for SDP than random donor platelets as they are associated with low risk of transfusion-transmitted diseases and also alloimmunization.

Generally, apheresis procedures are well tolerated. At times, adverse events of varying severity may occur during or after the procedure. These adverse events are divided into local and systemic reactions [3]. Local reactions are caused by the damage of blood vessel during phlebotomy procedure resulting in accumulation of blood outside the veins called as haematomas. These haematomas are associated with bruising, discolouration, local pain and swelling [3,4]. Systemic reactions are mainly vasovagal reactions that can be triggered by the pain of vein-puncture or by the anxiety and state of tension of undergoing the donation etc., [5]. These are characterised by the pallor, sweating, dizziness, nausea, hypotension and syncope. Citrate toxicity due to hypocalcaemia entails perioral paresthesia of the extremities, tremors, dizziness, chills, tetany and seizure [5]. As compared to whole blood donors, the SDP donors are far less and any adverse reaction in them will make the subsequent recruitment of the SDP donors difficult. The aim of this study was to identify the profile of platelet donors and the parameters of plateletpheresis procedure in correlation with the adverse events resulting from plateletpheresis donation.

MATERIALS AND METHODS

This retrospective study was carried out from November 2014 to June 2018. Data was collected from the records maintained by the Department of IHBT in a tertiary care hospital in Southern India. A total of 615 SDP procedures were performed during study period. Both continuous and intermittent flow centrifugation cell separators (Fresenius Kabi and Trima Accel) were used for performing procedures. All donations were collected from peripheral venous access in the cubital fossa using 16 gauze needle, with required aseptic precautions. Donors were selected as per the SOP criteria for SDP procedure in accordance to our hospital protocol such as weight 60 kg or more, age between 18 to 60 years, Hb 12.5 g/dL and platelet count >1.5 lacs/dL.

As per Drugs and cosmetics act guidelines, if donors used aspirin containing medication within 36 hours were deferred. Interval between procedures should be at least 48 hours and not more than twice a week or 24 times in a year. All the donors were free from any illness and tested negative for HIV, Hep. B, HCV, Syphilis, and Malaria.

STATISTICAL ANALYSIS

Association between platelet count, ACD volume used for each procedure and citrate toxicity was studied by calculating "r"-value (Pearson correlation) using software Microsoft Excel 2007 and p-value by using paired t-test.

RESULTS

A total of 615 plateletpheresis procedures were performed during the study period. All the donors were males. Age range of SDP donors varied from 19 years to 48 years. An 88.93% of donors were between 18 years to 35 years. Majority of the donors (529) were first-time donors and 41 donors were repeat donors [Table/Fig-1].

Association between platelet count, ACD volume used for each procedure and citrate toxicity is shown in [Table/Fig-2]. Platelet counts of the donors ranged from 1.6 to 4.5 lacs/dL. Higher the platelet count of the donor before SDP procedure was associated

with low ACD volume consumption, less duration of the procedure and reduced citrate toxicity reactions as shown in [Table/Fig-3]. Amongst the selected 615 procedures, a total of 25 (4.06%) donors had some type of adverse event, 15 (2.43%) had citrate related toxicity reactions, 2 (0.32%) had a vasovagal reactions, 8 (1.3%) had haematomas [Table/Fig-4]. Among the donors who suffered adverse events, 22 (88%) were first-time platelet donors and 3 (12%) were repeat donors. All the reactions were mild and well managed. Only one case had a severe reaction of convulsion (0.16%) during the end of the procedure and recovered immediately after removing the needle and elevating the foot end. Later on, the donor revealed that he had a seizure disorder during his childhood for which he took treatment 15 years back and was asymptomatic since then.

Type of donors	No. (%)
First time donors	529 (92.8%)
Repeat donors 37 donors-donated twice 37*2=74 4 donors donated thrice 4*3=12	41 (7.2%)
Total donors (615 SDP procedures)	570

[Table/Fig-1]: Types of donors.

Parameter	Parameter	r-value	Interpretation	p-value
Donor platelet count	Donor reactions	-0.96	Strong negative correlation	0.001
Donor platelet count	ACD volume consumed	-0.96	Strong negative correlation	0.001
Donor platelet count	Duration of the procedure	-0.95	Strong negative correlation	0.001
ACD volume consumed	Citrate toxicity	0.99	Strong positive correlation	0.001
Duration of the procedure	ACD volume consumed	0.99	Strong positive correlation	0.001

[Table/Fig-2]: Pearson's correlation between different parameters in SDP procedure.

Platelet count lacs/dL	No. of SDP Donors	Percentage %	Duration	ACD consumption in mL	Donor reactions
1.5-2.0	92	14.90	61-90 min	300-400	9-Citrate toxicity 2-Hematomas
2.1-2.5	172	27.86	60 min	250-300	4-Citrate toxicity 2-Hematomas
2.6-3.0	180	29.16	50 min	231-260	2-Citrate toxicity 2-Hematomas 1-sweating
3.1-3.5	95	15.39	Under 45 min	201-230	1-Hematoma 1-Vomiting
3.6-4.0	74	11.98	Under 40 min	180-200	1-Hematoma
4.0-4.5	2	0.32	Under 35 min	170-180	Nil
Total	615	100			15-Citrate toxicity 8-Hematomas 2-others

[Table/Fig-3]: SDP procedure details and occurence of adverse reactions.

Types	Reaction	No.
Citrate related toxicity causes	Peri-oral paresthesia	12
	Convulsion	1
	Muscle spam	2
Vaso-vagal causes	Vomiting	1
	Sweating	1
Local causes	Hematomas (swelling, bruising, pain)	8
Total	25 (4.06%) (Severe adverse reactions-0.16%)	

[Table/Fig-4]: Adverse reactions.

DISCUSSION

The present study main focus was to identify the profile of platelet donors and the parameters of plateletpheresis donations as well as the adverse events resulting from plateletpheresis donation. Even though there is no evidence that these procedures are associated with severe complications, different reports from medical literature shows variation in the frequency of occurence of adverse events during the donation [6].

In the present study, majority of the donors were under the age of 35 years (88.93%) which was in agreement with the studies in literature [7-9]. However in a study by Barbosa MH et al., the predominant donor age range was 40-49 years [10].

In this study, total of 4.06% (25/570) donors had some kind of adverse events. Among them, 22 (88%) were first-time platelet donors and 3 (12%) were repeat donors. In a study by Arora D et al., 13 (3.48%) were first-time platelet donors and 2 (0.58%) were repeat donors among the 15 donors who had adverse event out of 344 donors [7]. The study by Crocco I et al., showed only 0.68% (18/2,641) which is a very low incidence of adverse events among the plateletpheresis donors as this study has not included the local reactions like haematomas as adverse events [6]. The study conducted by Patidar GK et al., had a very high incidence of adverse events of 18% (90/500) among the plateletpheresis donors [11].

It was observed that the lower the donor platelet count, the more were the occurence of citrate toxicity related adverse events among donors. This could be due to increased duration of procedure which results in increased infusion of ACD (anticoagulant) to the donor. A study revealed that adverse events occurred in plateletpheresis procedures which took more time (mean 77.1 min) compared to those without adverse events [12]. All the donors who had citrate related adverse events were first-time donors accounting for 2.43% (15/615). Citrate related adverse events in other studies conducted by Philip J et al., Crooco I et al., Patidar GK et al., and Khajuria K et al., were 0.96%, 0.38%, 9.0% and 3.03% respectively [5,6,11,13].

In the present study, one case of convulsion was observed which was a severe reaction and accounts for 0.16% (1/615). Further, this could have been prevented provided the donor had not concealed his past history of seizure disorder. Despotis GJ et al., reported 0.24% of severe adverse events in plateletpheresis donors [14].

Vasovagal reactions and haematomas have no relation to platelet count of donors or ACD consumed by the donors. There incidence in SDP donors may be similar to whole blood donors. In our study, the incidence of vasovagal reactions was 0.32% (2/615) among first-time donors which was in agreement with the study conducted by Reiss RF et al., [15], where the vasovagal reactions varied from 0.32% to 0.64% among different age groups. In a study conducted by Crocco I et al., the incidence of vasovagal reactions was 0.68% (18/2,641) [6].

In our study, local reactions like haematomas were observed in 1.3% (8/615), whereas it was 1.16% (4/344) and 1.51% (1/66) in a study by Arora D et al., and Khajuria K et al., respectively [7,13]. Tomita T et al., Observed difference between apheresis donors and whole blood donors in the incidence of vasovagal reactions increased with age for SDP and not same with the whole blood donations [16]. Formation of haematomas can be considered if there are any factors such as thin or deep veins in the venipuncture site, going through the vein by an under experienced nurse/technologist causing damage to the vessel or extravasation of red cells during return phase, improper care after the initial bleeding was stopped from venipuncture are associated with the formation of haematoma [10,17]. In this study, female SDP donors were not included, because the number of female donors coming for SDP donation is very less and all of them were deferred for not fitting in the selection criteria and in general for low haemoglobin. The studies in the literature also documented minimal female SDP donors [8].

CONCLUSION

The overall rate of acute adverse events, among healthy SDP donors in our study was very low. Citrate toxicity was reduced significantly in the donors with platelet count 2.5-4.5 lac/dL in our study. All the adverse events were managed very well. None required hospitalisation of the SDP donor. Vasovagal reactions could be managed easily similar to those occurring during whole blood donations. Vein puncture related local reactions can further be minimised to some extent by allowing only an experienced professional to perform the procedure. This low rate of mild adverse events in our study underlies safety of donors of plateletpheresis.

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