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Era of blood component therapy: Time for mandatory pre-donation platelet count for maximizing donor safety and optimizing quality of platelets

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ABSTRACT

Blood bank regulatory agencies including the Drug and Cosmetics Act (DCA) of India do not mandate a predonation platelet count in whole blood donation. Mandating such practice will definitely optimize the quality of random donor platelets (RDP) in terms of platelet yield and patient therapeutic benefit. We observed poor platelet yield in RDP concentrates prepared at our center with a significant number not meeting the DCA guideline of $\geqslant 4.5 \times 10^{10}$ per bag processed from 450 ml of whole blood. Therefore we planned this study to evaluate the pre-donation hematological values in our blood donor population and effect of these values on the quality of platelet concentrates.

The prospective study included 221 blood donors eligible for donating 450 ml of whole blood (WB). Following the departmental standard operating procedure (SOP) RDPs were prepared using the 'Top & Bottom' quadruple bag system and automated component extractor. Quality of RDP was assessed as per departmental protocol. All results were recorded and subsequently transcribed to SPSS working sheet.

A significant ($p < 0.001$) decrement of donor blood counts has been observed after WB donation. Mean donor Hb and platelets reduced by 0.72 g/dl and 22.1×10^6/ml respectively. Quality of RDPs in terms of platelet yield was significantly better ($p < 0.001$) when donor platelet count was $>200 \times 10^6$/ml. Although platelet yield significantly correlated with the donor platelet count however quality of RDPs in terms of red cell contamination showed no correlation with the donor hematocrit.

Platelet yield in random donor platelets is a concern in Eastern India. A platelet yield of 4.5×10^{10} per bag as mandated by the DCA of India was only achieved when the donor platelet count was $>200 \times 10^6$/ml. Posttransfusion platelet recovery (PPR) was unsatisfactory in the transfused patient. Introduction of pre-donation platelet count in whole blood donation will maximize donor safety and optimize patient platelet transfusion management.

1. Introduction

Blood bank regulatory agencies including the Drug and Cosmetics Act (DCA) of India do not mandate a complete blood count as part of whole blood (WB) donor screening program [1]. A hemoglobin (Hb) value of $\geqslant 12.5$ g/dl can prevent donor iatrogenic anemia and optimize quality of red blood cells but quality of platelets prepared from the same unit needs investigation [2,3]. In today's era of component therapy a pre-donation platelet count may be useful to ensure platelet quality and thereby patient well being. Platelet count in an individual is population specific and may vary from region to region [4–6]. Therefore

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donors with low platelet count may suffer iatrogenic thrombocytopenia after a blood donation. We observed poor platelet yield in the random donor platelet (RDP) concentrates prepared at our center. A significant number of RDPs could not meet the DCA recommended value of $\geqslant 4.5 \times 10^{10}$ per bag processed from 450 ml of whole blood Therefore we planned this prospective study to evaluate the pre-donation hematological values in our blood donor population and effect of these values on the quality of RDPs.

2. Materials and methods

The prospective study conducted between September 2011 and January 2013 included 221 randomly accepted blood donors between 19 and 51 years of age, weighing >60 kg and eligible for donating 450 ml of WB. Details of donation procedure and testing were explained to each donor and due consent taken from them before the donation. To measure pre- and post- donation hematological values, whole blood sample in EDTA vials were collected before and just after whole blood donation. To obtain the desired platelet volume and optimum platelets in the RDP units, platelets were prepared only from the 450 ml WB collections. Following the departmental standard operating procedures (SOPs), WB (450 ml) was collected in the 'Top & Bottom' quadruple bag system (Terumo Penpol, Trivandrum, India) and separated within 6 h using the T-ACE II + automated component extractor (Terumo Penpol, Trivandrum, India). Due to increasing demand most platelets are issued within 3rd or 4th day therefore quality testing of RDP concentrates was performed on the 2nd or 3rd day of preparation.

Donor pre- and post-donation hematological parameters such as Hb, hematocrit (Hct), platelet and WBC counts and blood counts (platelet, red cell and WBC) of RDP concentrates were measured using a calibrated automated cell counter (Advia, Siemens, Germany). All results were recorded in respective registers and subsequently transcribed to SPSS working sheet.

2.1. Statistical analysis

Statistical analysis was done using the SPSS statistical package (version 13, Microsoft, Seattle, WA, USA). All results were calculated as mean ± SD and a '*p*' value of <0.05 was considered statistically significant. Mean values were compared using the unpaired or paired Student's t test as appropriate. Correlation coefficients were calculated using the Pearson correlation analysis.

3. Results

A total of 11,207 whole blood units were collected during the study period of which 221 (1.97%) healthy donors (215 males, 6 females) with mean age 34.7 ± 10.9 years and weighing 71.4 ± 6.8 kg were included in the study and quality analysis program. Of the total 11,207 whole blood collected 7509 (67%) were 450 ml collections of which 7103 (94.6%) were processed into platelets. A significant ($p < 0.001$) decrement of donor blood counts has been observed after WB donation. The mean reduction of donor Hb and platelets were 0.72 g/dl and 22.1×10^6/ml respectively (Table 1). Postdonation platelet counts of 9 donors were $<100 \times 10^6$/ml and by definition suffered from iatrogenic thrombocytopenia. Quality of RDPs in terms of platelet yield was significantly better ($p < 0.001$) when the donor platelet count was $>200 \times 10^6$/ml. A poor platelet yield was observed when the platelet count was $\leqslant 150 \times 10^6$/ml (Table 2). Although platelet yield significantly correlated with the donor platelet count ($r = 0.87$, $p < 0.001$) however quality of RDPs in terms of red cell contamination showed no correlation with the donor hematocrit ($r = -0.01$, $p = 0.89$) (Figs. 1 and 2).

4. Discussion

Platelet yield in random donor platelets is a concern in Eastern India. Despite standardized process flow and operating procedures low donor platelet count influenced the quality of RDPs significantly. A platelet yield of $\geqslant 4.5 \times 10^{10}$ per bag processed from 450 ml of whole blood as mandated by the DCA of India was only achieved when the donor platelet count was $>200 \times 10^6$/ml. However such category of donors constituted only 16.7% in the present study. With regards to posttransfusion platelet recovery (PPR) observed in 7 new patients of non-transfused aplastic anemia the PPR was unsatisfactory. With a dose of 1 RPD unit per 10 kg of body weight the mean PPR was observed to be 17% after 20 h of transfusion. However most of these RDP units did not met the DCA criteria of $\geqslant 4.5 \times 10^{10}$ per bag. Physician's worry about poor platelet increment in these 7 patients was a concern to the blood bank and so we planned to perform the present study to determine the cause of such poor transfusion outcome. The mean platelet yield was 1.8×10^{10} when the donor pre-platelet count was $<150 \times 10^6$/ml which indicated that 10 units of RDPs or even more may be required to transfuse a single hemostatic platelet dose. Although studies on donor platelet count have been well documented in plateletpheresis program however such observation in whole blood collection is least explored [7–9]. In a study in Northern India, the authors observed mean platelet yield of $7.6 \pm 2.97 \times 10^{10}$/unit and $7.3 \pm 2.98 \times 10^{10}$/unit in platelet rich plasma–platelet concentrates (PRP–PC) and buffy coat–platelet concentrates (BC–PC) respectively which was comparable and not statistically significant [10]. Others reported higher platelet yield and platelet recovery with PRP–PC [11–13]. We prepare RDPs using the BC method and owing to the poor platelet counts in our donor population only 14.7% of our units could meet the DCA criteria of $\geqslant 4.5 \times 10^{10}$/unit.

We observed a significant ($p < 0.001$) decrement of donor blood counts after WB donation. The hemoglobin and platelets reduced by 0.72 g/dl and 22.1×10^6/ml respectively but none of our donors had a hemoglobin decrement of >1 g/dl. Since study on such subject is very scarce in the literature so it was difficult to comment whether such significant reduction is of concern. Das et al. observed a significant hemoglobin, platelet and

Table 1
Hematological values before and after whole blood donation ($N = 221$).

Parameters	Pre-donation		Post-donation		Difference	p-Value
	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	
Hb (g/dl)	14 ± 0.92	12.5–17.4	13.2 ± 0.93	11.8–16.2	0.72 ± 0.36	<0.001
Hct (%)	44.4 ± 3.5	37.5–59.4	42.1 ± 3.2	36.3–53	2.3 ± 1.3	<0.001
PLT ($\times 10^6$/ml)	162.8 ± 33.2	97–278	140.7 ± 31.7	78–213	22.1 ± 13.4	<0.001
WBC($\times 10^3$/ml)	7.9 ± 2.1	4.4–13.3	6.6 ± 1.8	2.8–12	1.3 ± 1.8	<0.001
MPV (μm^3)	10.7 ± 2.6	6.9–18.2	10.8 ± 2.5	6.8–18.4	−0.03 ± 0.12	0.24
PDW (%)	15.4 ± 2.9	9.4–18.7	15.2 ± 2.7	9–17.7	0.4 ± 1.2	0.11

SD: standard deviation.

Table 2
Donor platelet count and quality of random donor platelets.

PLT count range ($\times 10^6$/ml) ($N = 221$)	Donor blood counts				Quality of RDP		
	PLT ($\times 10^6$/ml)	Hb (g/dl)	Hct (%)	Volume (ml)	pH	PLT yield ($\times 10^{10}$)	WBC ($\times 10^{9}$)
100–150 ($N = 78$)	127.8 ± 14.6	14.3 ± 0.93	44.5 ± 3.6	56 ± 7.2	7.02 ± 0.4	1.8 ± 0.49	4.3 ± 2.1
151–200($N = 106$)	170.7 ± 14.4	13.9 ± 0.87	44.1 ± 3.1	55 ± 6.9	7 ± 0.2	3.4 ± 0.74	3.6 ± 2.9
>200 ($N = 37$)	216.1 ± 16.2	14.1 ± 0.99	44.4 ± 3.7	56 ± 7.1	7.02 ± 0.2	4.7 ± 0.83	3.9 ± 2.6

All values expressed as Mean ± SD.
$p < 0.001$ for all pairs of platelet yield.

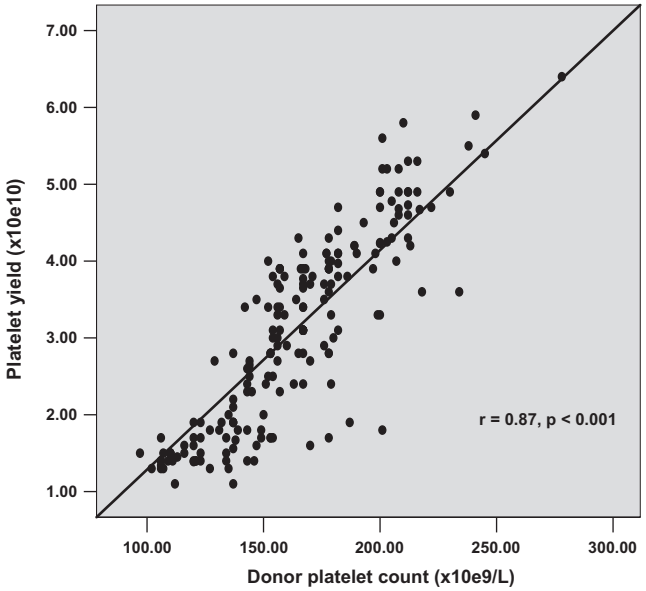

Fig. 1. The correlation between donor platelet count and platelet yield in random donor platelets ($N = 221$). A significant Pearson correlation observed ($r = 0.87$, $p < 0.001$).

WBC decrement of 0.8 g/dl, 67.6 × 10^6/ml and 1.1 × 10^3/ml respectively in their plateletpheresis donors [14]. With regards to optimization of blood component therapy, clinical benefits in patients and ultimate donor safety it may be suggested to mandate pre-donation platelet count before whole blood donation. Such practice will definitely prevent donor iatrogenic thrombocytopenia and maintain quality of platelets.

Various studies on plateletpheresis have demonstrated that the platelet yield is predominantly dependent on the donor platelet count [8,9,15]. Our results with regards to RDPs are also in agreement with these observations. There was a direct correlation between the platelet yield in RDPs and the pre-donation platelet count (Fig. 1). However high donor Hb or Hct did not affect the quality of RDPs in term of red cell contamination (Fig. 2).

We conclude that in this era of component therapy pre-donation platelet count of donors should be made mandatory in whole blood donation particularly in regions where donor platelet count is low. This will not only ensure

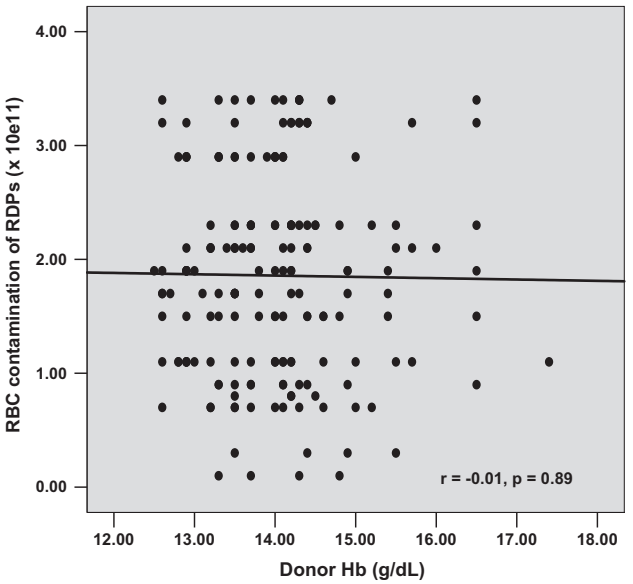

Fig. 2. The correlation between donor Hb and red cell contamination of RDPs ($N = 221$). Pearson correlation not significant ($r = -0.01$, $p = 0.89$).

maximum donor safety but will also optimize patient platelet transfusion management.

References

[1] Malik V. Drugs & Cosmetics Act. 13th ed. Lucknow (India): Eastern Book Company; 2001.

[2] Council of Europe. Guide to the preparation, use and quality assurance of blood components. 4th ed. Germany; 1998.

[3] Brecher ME. Technical manual. 15th ed. USA: American Association of Blood Banks; 2005.

[4] Biino G, Balduini C, Casula L, et al. Analysis of 12,517 inhabitants of a Sardinian geographic isolate reveals that predispositions to thrombocytopenia and thrombocytosis are inherited traits. Haematologica 2011;96:96–101.

[5] Segal JB, Moliterno AR. Platelet counts differ by sex, ethnicity, and age in the United States. Ann Epidemiol 2006;16:123–30.

[6] Buckley MF, James JW, Brown DE, Whyte GS, Dean MG, Chesterman CN, et al. A novel approach to the assessment of variations in the human platelet count. Thromb Haemostasis 2000;83:480–4.

[7] Goodnough LT, Kuter D, McCollough J, Brecher ME. Apheresis platelets: emerging issues related to donor platelet count, apheresis platelet yield, and platelet transfusion dose. J Clin Apheresis 1998;13:114–9.

[8] Goodnough LT, Ali S, Despotis G, et al. Economic impact of donor platelet count and platelet yield in apheresis products: relevance for emerging issues in platelet transfusion therapy. Vox Sang 1999;76:43–9.

[9] Das SS, Chaudhary RK, Shukla JS. Factors influencing yield of plateletpheresis using intermittent flow cell separator. Clin Lab Haematol 2005;27:316–9.

[10] Singh RP, Marwaha N, Malhotra P, Dash S. Quality assessment of platelet concentrates prepared by platelet rich plasma–platelet concentrate, buffy coat poor–platelet concentrate (BC–PC) and apheresis-PC methods. Asian J Transfus Sci 2009;3:86–94.

[11] Fijnheer R, Pietersz RN, de Korte D, Gouwerok CW, Dekker WJ, Reesink HW, et al. Platelet activation during preparation of platelet concentrate: a comparison of platelet rich plasma and the buffy coat methods. Transfusion 1990;30:634–8.

[12] Hirosue A, Yamamoto K, Shiraki H, Kiyokawa H, Maeda Y, Yoshinari M. Preparation of white cell poor blood components using a quadruple bag system. Transfusion 1988;28:261–4.

[13] Keegan T, Heaton A, Holme S, Owens M, Nelson E, Carmen R. Paired comparison of platelet concentrates prepared from platelet rich plasma and buff y coats using a new technique with ^{111}In and ^{51}Cr. Transfusion 1992;32:113–20.

[14] Das SS, Chaudhary R, Verma SK, Ojha S, Khetan D. Pre- and post-donation hematological values in healthy donors undergoing plateletpheresis with five different systems. Blood Transfus 2009;7:188–92.

[15] Guerrero-Rivera S, Gutierrez-Espindola G, Talavera JO, Meillon-Garcia LA, Pedraza-Echevarria M, Pizzuto-Chavez J. Hemoglobin and platelet count effect on platelet yields in plateletpheresis. Arch Med Res 2003;34:120–2.