Double Dose Plateletpheresis: A Savior to Shrinking Donor Pool and Platelet Inventory Management

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Received: 9 June 2017 / Accepted: 10 January 2018 / Published online: 20 January 2018
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Abstract The double dose plateletpheresis (DDP) is considered to be a cost effective way of preparing platelets, owing to the low incidence of infectious complications and by also minimizing allogeneic donor exposure to the patients. We aimed at collecting DDP at our center and study its effect on donor hematological parameters, evaluate the product quality and the adverse donor reactions thereafter. Double Dose Platelet was collected from 160 eligible apheresis donors on Amicus cell separator (Fenwal, Inc. Three Corporate Drive Lake Zurich, IL, USA). The donor hematological parameters, product yield, adverse effects on the donors, collection efficiency (CE) and collection rate of the machine were noted. A total of 160 DDPs were collected. The total blood volume processed to achieve the yield of 6.0×10^{11} was 3673.5 ± 276.56 mL. The average yield achieved was $6.14 \pm 0.26 \times 10^{11}$. The average run time was 68.05 ± 6.25 min. Total ACD used was 408.33 ± 33.81 mL. We observed significant relation of pre-donation donor platelet count and platelet yield ($p < 0.001$). The CE was $78.09 \pm 5.15\%$. There was a significant drop in the post DDP platelet count ($p < 0.01$) causing no adverse effect. Fourteen donors (8.75%) experienced mild citrate related adverse events. DDP does not lead to major adverse effects and post DDP hematological

parameters are also within the acceptable range. It also helps to maintain apheresis platelet inventory, reduce donor exposure, reduce donor requirement and reduce the cost of the product.

Keywords Apheresis · Double dose apheresis · Plateletpheresis · Donor selection criteria

Introduction

In recent years, the use of platelets (PLT) obtained by single donor apheresis has grown steadily over the Random Donor Platelets (RDP) [1]. Apheresis platelets are preferred over RDPs as it provides lesser number of donor exposures, consequent reduction in transfusion transmitted diseases, transfusion reactions and possibly alloimmunization [2]. Patients with confirmed immune mediated platelet refractoriness due to anti-HLA (Human Leukocyte Antigen) antibodies should receive HLA matched platelets or platelets negative for the corresponding antigen or cross-match compatible platelets [3]. Use of apheresis platelet permits transfusion of platelets from HLA matched donors.

As platelets are stored at room temperature and the risk for bacterial growth limits the shelf life of platelet units to only 5 days, maintaining platelet inventory is a challenging task. The stringent exclusion criteria for PLT donation have made donor recruitment and retention more difficult [4, 5]. Technical advances in automated cell separators have improved the quality and productivity of apheresis platelet collection [6]. The latest generation of apheresis machines—the Trima (Caridian BCT), the Amicus (Fenwal), or the COMTEC (Fresenius)—have demonstrated significant progress with respect to collection efficiency, higher yield, donor comfort and better ACD ratio. [7, 8]. To reduce the

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cost, risk of multiple donor exposure and to maintain the inventory, the practice of collecting double-dose of platelets (DDP) is on the rise [9–11].

Our aim was to collect DDP at our centre & study the effect of DDP collection on donor hematological parameters, evaluate the component quality and the adverse donor reactions thereafter.

Materials and Methods

A prospective study on DDP collection to study its effect on pre and post donation hematological parameters on the donors, adverse donor reactions and yield of platelets was conducted in the department of Transfusion Medicine, Indraprastha Apollo Hospital, New Delhi from 1st September 2014 to 31st August 2015. The study was approved by the institutional ethics committee.

Donor Characteristics and Testing

All donors who met the eligibility criteria for plateletpheresis as per the directorate general of health services (DGHS) guidelines were enrolled in the study. As, there is no consensus Indian or American Association of Blood Banks (AABB) guidelines for DDP collection, a departmental SOP was prepared and the pre-donation platelet count of the donor was set to $\geq 250 \times 10^3/\mu\text{L}$. According to the United States Food and Drug Administration (USFDA) the interval between two consecutive apheresis DDP should be 7 days if required [12]. After explaining the donor about the procedure, informed consent was obtained from each of the donors and 3–4 mL blood sample was withdrawn in 2 separate Ethylenediaminetetraacetic acid (EDTA) vials. One vial was used for doing blood grouping via tube method and performing complete blood count (CBC) which included hemoglobin (Hb), hematocrit, White Blood Cell (WBC), PLT and Red Blood Cell (RBC) count using Beckman coulter (Miami, Florida).

The other vial was used for testing the donor for anti-HIV (I and II), Anti HCV, HbsAg, syphilis and malaria as per the Drugs and Cosmetic Act 1945 [13]. Anti-HIV (I and II), Anti HCV, HbsAg were tested by Chemiluminescence Microparticle Immuno Assay (CMIA) by Abbot Architect (Abbot Laboratories, Abbot Park, IL, USA). Syphilis was tested by Carbogen RPR card test (Tulip Diagnostics LTD, Uttarakhand, India) and Malaria was tested by rapid method using Malascan (Zephyr Biomedicals, Uttarakhand, India).

Apheresis Instrument

Amicus software version 3.2 (Fenwal, Inc. Three Corporate Drive Lake Zurich, IL, USA) single-needle procedure was

used for DDP collection. Anticoagulant to whole blood ratio was maintained at 1:8–1:11. The inlet and outlet blood flow was set between 60 and 100 mL/min.

The following data were entered into the cell separator program: donor weight, sex, height, Hb and pre-donation PLT count. The target yield of 6.0×10^{11} was set.

The separation time, processed blood volume to reach the PLT target yield, and the acid citrate dextrose-A (ACD-A) volume used and the component volume was recorded.

Post Procedure Sample Collection

Sampling From Donor

After the procedure, the donor was made to rest for approximately 30 min [14]. After 30 min, 2 mL of blood sample was withdrawn in EDTA vial for measuring the Hb, platelet count, haematocrit and RBC count using Beckman coulter (Miami, Florida).

Sampling From the Component Bag

Following collection of DDP, the component was allowed to rest for 2 h to ensure optimum disaggregation of PLT before sampling. Then approximately 1 mL sample was collected in EDTA vial after thorough stripping of the segment to ensure correct representative of the component. The samples were then mixed thoroughly and pH, PLT and WBC counts were measured. PLT and WBC count were measured by Beckman coulter (Miami, Florida) and pH was measured by pH strip (Combistix SG, SIEMENS, Vadodara-390019, India).

Platelet Yield was calculated as follows:

$$\text{Component platelet count } (\times 10^3/\mu\text{L}) \times \text{Component volume (mL)} \times \text{Conversion factor (1000)}$$

Collection Efficacy (CE) of the machine was be calculated as follows:

$$[\text{PLT yield/total PLT processed (TPP)}] \times 100 \text{ [15].}$$

$$\text{TPP} = [\text{pre} + \text{post PLT count}/2] \times \text{total blood processed (mL)} \times \text{conversion factor (1000)} \text{ [16].}$$

$$\text{Total blood volume processed} = \text{blood volume processed} - \text{anticoagulant volume.}$$

$$\text{Collection Rate (CR)} = \text{PLT yield/separation time [17].}$$

Statistical Analysis

Results were tabulated in Microsoft Office Excel worksheet and descriptive variables were analysed in terms of mean, median and/or standard deviations (SD). Wilcoxon signed rank test was used to compare the value of a variable at pre

and post-DDP apheresis and Wilcoxon rank sum test was used to compare the variables between groups created by yield. Statistical software SPSS version 17.0 and R-3.2.0 was used for all the statistical analysis. For all statistical analysis, a p value of less than 0.05 was considered significant.

Results

During the study period, 471 donors were screened for platelet apheresis. Out of these, only 180 donors were eligible for DDP donation. Of the 180 donors, 160 gave consent for DDP donation. All of them were males and none of them was a repeat donor. The average age of the donors was 31.59 ± 7.49 years. The average height and weight was 163.61 ± 8.72 cm and 69.6 ± 5.86 kg respectively. Majority of them had blood group B Rh D positive (51.25%, $N = 82$), followed by O Rh D positive (22.5%, $N = 36$), A Rh D positive (16.25% $N = 26$) and AB Rh D positive % (10% $N = 16$). The baseline CBC counts and post procedure CBC count of 160 donors are shown in Table 1. The Apheresis procedure and component details are shown in Table 2.

None of the parameters except platelet count showed a significant drop after DDP donation. Seventeen donors out of 160 had adverse donor reactions (10.62%). Fourteen (8.75%) complained of citrate related adverse events during the donation. All of them had peri-oral tingling and numbness. Three donor out of 160 (1.87%) experienced hematoma formation at the phlebotomy site in immediate post donation period.

The relationship between pre-procedure donor platelet count and component yield is shown in Fig. 1.

Discussion

Apheresis platelets offer advantage in terms of reduced infectious complications, transfusion reaction rate, transfusion frequency in patients with bone marrow

Table 2 Apheresis procedure and Component details

Parameter	Mean $\pm$ SD
Separation time (min)	68.05 $\pm$ 6.25
Total blood volume processed (mL)	3673.5 $\pm$ 276.56
ACD volume used (mL)	408.33 $\pm$ 33.8 1
Platelet volume (mL)	435.09 $\pm$ 6.10
Platelet yield ($\times 10^{11}$)	6.14 $\pm$ 0.26
Residual WBC count ($\times 10^6$)	1.21 $\pm$ 0.84
pH	6.99 $\pm$ 0.22
Collection efficacy (%)	78.09 $\pm$ 5.15
Collection rate (PLT $\times 10^{11}$ /mL)	0.091 $\pm$ 0.032

suppression, better leukodepletion and in the treatment and prevention of alloimmunization [18]. They also show better swirling and platelet count than platelet rich plasma-platelet concentrates (PRP-PCs) and Buffy coat- platelet concentrates (BC-PCs) [19].

The emerging safety measures for platelets like bacterial screening and exclusion of female donors from donating plasma containing components to prevent transfusion related acute lung injury (TRALI) are well known [20, 21]. These concerns about platelet safety will further reduce the donor pool and increase the complexity of the platelet collection. On the contrary, need of Single Donor Platelet (SDP) is increasing leading to interest in collection of DDP.

According to Wollersheim et al. [5] body weight is an important determining factor for the platelet yield. Donors, who weigh less than 65 kg, have a lower platelet yield in DDP. However, in our study we did not find any significant correlation between donors' weight and platelet yield ($p = 0.82$). We did not find significant correlation between donors' height and age with platelet yield either ($p = 0.21$) ($p = 0.61$). They also showed a positive correlation between the donors' pre-donation platelet count with the platelet yield in DDP. They recommended that donors with a pre-donation count of below $225 \times 10^3/\mu\text{L}$ should be deferred for DDP as the platelet yield from such donors after DDP was considerably low. Glicher and Smith [22] found that DDP can be obtained when the donor platelet count is $\geq 250 \times 10^3/\mu\text{L}$. Chaudhary et al. [23] and Jaipian et al. [24] also considered the pre-procedure platelet count of $\geq 250 \times 10^3/\mu\text{L}$ for DDP collection. Accordingly, we considered only those donors for DDP whose pre-donation platelet count was $\geq 250 \times 10^3/\mu\text{L}$. There was a significant positive correlation of the platelet yield with the pre-donation count in our study ($p < 0.001$) which is in line with what Wollersheim et al. have demonstrated.

In a study by Fontana et al. [25] the PLT yield in DDP by Amicus was 6.06×10^{11} . Similar were the findings by

Table 1 Pre and post donation CBC of the donors

Parameter	Mean $\pm$ SD		P value
	Pre procedure	Post procedure	
Haemoglobin (gm/dL)	14.29 $\pm$ 0.97	14.24 $\pm$ 1.01	0.14
PCV (%)	42.97 $\pm$ 2.85	42.81 $\pm$ 3.20	0.72
Platelet count ($\times 10^3/\mu\text{L}$)	308 $\pm$ 0.27	176 $\pm$ 0.29	< 0.05
RBC count ($\times 10^6/\mu\text{L}$)	5.16 $\pm$ 0.33	5.14 $\pm$ 0.34	0.86
WBC count ($\times 10^3/\mu\text{L}$)	7.47 $\pm$ 1.04	7.94 $\pm$ 2.51	1.65

Fig. 1 Relationship between pre-procedure donor platelet count and component yield

Keklik et al. [26] as well ($6.1 \pm 0.9 \times 10^{11}$). The yield was $7.24 \pm 0.53 \times 10^{11}$ in study by Jaipian et al. [24] on DDP. The platelet yield in our study ($6.14 \pm 0.26 \times 10^{11}$) was comparable to that of Fontana et al. [25] and Keklik et al. [26] but was lower when compared to the study by Jaipian et al. [24]. The reason behind this could be attributed to the higher mean pre-procedure platelet count ($339 \times 10^3/\mu\text{L}$ vs. $308 \times 10^3/\mu\text{L}$) and higher target yield (6.5×10^{11}) in the study by Jaipian et al. as compared to ours. Our DDP yield was higher than that obtained by Chaudhary et al. [23] ($5.4 \pm 0.6 \times 10^{11}$) as their target yield was lower than our study (5.5×10^{11} vs. 6×10^{11}).

The donor comfort is vital during the DDP collection which is mainly related to the time taken for the procedure to complete. Apheresis machines with different mechanism take different time for DDP collection. The average run time were 62, 70, 78 and 89 min as noted by Keklik et al., Chaudhary et al., Gurek et al. and Fontana et al. [1, 11, 23, 26] respectively. In our study, the average run time was 68.05 min which is consistent with the finding of Chaudhary et al. [23]. Lesser time was noted in the study by Keklik et al. [26] as they had used double needle system for DDP collection as compared to the single needle system used by us. The longer time duration seen by Fontana et al. [1] and Gurek et al. [11] as compared to our study might be due to the lesser mean pre-procedure platelet count among their donors when compared to our study ($262 \times 10^3/\mu\text{L}$ vs. $297 \times 10^3/\mu\text{L}$ vs. $308 \times 10^3/\mu\text{L}$).

Collection efficiency has no relation with target platelet yield. As target yield increases, total blood volume processed also increases and post platelet count decreases.

Different CEs are reported in the studies on DDP collection by single needle procedures on Amicus. The CE noted in our study was 78.09% whereas it was 59.7% as noted by Chaudhary et al. [23] and 85.31% as noted by Jaipian et al. [24].

Plateletpheresis procedure is generally associated with the loss of some amount of red cells and monitoring of Hb/Hct is vital after the plateletpheresis procedure. Flesch et al. [27] reported that post donation HCT was slightly elevated after DDP (41.2 ± 2.94 after apheresis vs. 40.6 ± 2.94 before apheresis) with Amicus. This might be due to haemoconcentration after plateletpheresis procedure. Chaudhary et al. [23] reported a significant drop in the Hb level post DDP with Amicus ($p = 0.03$). They could not find the cause behind it. In the contrary, we observed very minimal mean reduction in the HCT level post donation. (42.97 ± 2.85 vs. 42.81 ± 3.20) ($p = 0.74$) which was not significant.

DDP collection is associated with higher platelet loss in the donor. Measuring the post-procedure platelet count can help to assess the effect of DDP on the donor platelet count. In our study we found statistically significant reduction in the post DDP platelet count ($308 \times 10^3/\mu\text{L}$ vs. $176 \times 10^3/\mu\text{L}$) ($p = <0.01$). This finding is in accordance with the study performed by Jaipian et al. [23] ($339.18 \pm 33.72 \times 10^3/\mu\text{L}$ vs. $197.44 \pm 27.01 \times 10^3/\mu\text{L}$). He stated that none of the donors had a platelet count of $< 100 \times 10^3/\mu\text{L}$ after the procedure. In our study the least post-procedure platelet count observed was $129 \times 10^3/\mu\text{L}$. None of the donors experienced any clinical manifestations for decreased platelet counts.

Apheresis instruments are equipped with in built leukoreduction mechanism. One of the major advantages of apheresis platelets over RDPs is it provides a 3 log leukoreduced blood component which helps in prevention of transfusion refractoriness and alloimmunization. According to US FDA guidelines, residual WBC in DDP should be $< 8 \times 10^6$ [3]. Different studies have found varying residual WBC counts in their studies. The average residual WBC counts were 0.31×10^6 , 0.44×10^6 and $0.34 \pm 1.30 \times 10^6$ as noted by Wollersheim et al., Gurek et al. and Jaipian et al. respectively [5, 11, 24]. In our study, the residual leukocyte count was $1.21 \pm 0.85 \times 10^6$ which is higher than that noted in the above studies but still within the requirement of US FDA guidelines [12].

Anticoagulants used during apheresis provide consistent blood circulation in the apheresis kit and better component quality. On the contrary they are associated with citrate related adverse effects to the donors. Newer apheresis instruments provide minimum exposure of anticoagulants to the donors. The ACD-A used during DDP were 404, 393 and 387 mL as stated by Flesch et al., Jaipian et al. and Keklik et al. [24, 26, 27]. A volume of 408 mL of ACD-A used in our study is consistent with the above findings.

Chaudhary et al. [23] found the adverse effects in 15 out of 67 (22.4%) in DDP collection. They observed that it may be due to higher volume of ACD infused and whole blood processed as compared to single unit apheresis. They also found that informing the donor about the DDP collection increases the anxiety of the donor which can lead to adverse effects. Keklik et al. [26] showed that 8% of the donors experienced hypocalcemia. We observed citrate related adverse effects in 14 out of 160 (8.75%) donors in our study which is in line with the above results. All the donors experienced mild citrate related toxicity in the form of tingling and perioral numbness. These citrate related toxicity was corrected with oral calcium supplementation. In addition to these, we also noted a mild hematoma formation at the phlebotomy site among 3 donors out of 160 (1.87%). This may be due to the fact that the same vein in one arm is used for inflow and return which can lead to trauma resulting in hematoma formation. It was managed by applying firm pressure bandage. We did not find any relation of procedure time, ACD infused or Donor Body Mass Index with the donor adverse reactions.

Most of our DDP collection was done for multiply transfused patients like bone marrow transplant recipients and Dengue patients. We prepared two parts of the DDP product and issued to the same patient at different time. This helped us to reduce the donor exposure to the patient and also reduced the cost of the procedure to half.

Conclusion

In a country like India, where the donor pool is limited, DDP collection contributes greatly to the PLT inventory of a transfusion service. Use of apheresis donors can be optimized by carefully screening the donors. At our institute it helped to reduce the cost of the component as 2 units were collected from the same apheresis kit. DDP does not lead to any major adverse effects and post DDP hematological parameters of the donors are also within the acceptable range.

Limitations

As the collection of DDP was limited to a single apheresis machine, the comparison among the different platforms available for DDP collection could not be made. We could not compare the DDP with the Single Donor plateletapheresis.

Compliance with Ethical Standards

Conflict of Interest The authors have no conflict of interest.

Ethical Approval All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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