A Comparative Assessment of Quality of Platelet Concentrates Prepared by Buffy Coat Poor Platelet Concentrate Method and Apheresis Derived Platelet Concentrate Method

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Abstract Many blood centres in country don't have costly apheresis technology and rely heavily on the platelet production from whole blood donation. We conducted this study with the aim to compare the quality of platelet concentrates (PC) prepared by Buffy Coat derived (BC-PC) and apheresis derived platelet concentrate (Apheresis-PC). Our objective was to collect data by analysis of platelet concentrates prepared by BC-PC methods and Apheresis-PC methods in respect of swirling, volume, platelet count, WBC count and pH of the PC units and elaborate on the quality parameters. Tertiary Care Hospital and Medical College. We assessed a total of 200 BC-PC and 200 Apheresis-PC for their in vitro quality by observing swirling, volume of PC, platelet count/unit, WBC count/unit and pH, to see if they satisfy the recommended quality criteria. Data was analyzed using appropriate statistical technique under the guidance of biostatistician. Apheresis-PC units showed better swirling than BC-PC units (Chi square test; $P < 0.05$). There was a significant difference in proportion of units satisfying the required volume QC between the two methods (Chi-square test; $P < 0.05$). Apheresis-PC showed better adherence to the physiological pH values (Student's unpaired t test; $P < 0.05$). The units of BC-PC and Apheresis-PC did not show significant difference in proportion of units satisfying the Platelet count per unit and residual WBC count per count (Chi square;

P 0.203 and 0.617 respectively). There was comparable adherence to QC requirement for platelet count and WBC contamination in two methods. BC-PC were found to be adhering lesser to QC parameters for swirling, volume and pH, but found to be in required QC limits. BCPC can be used effectively in the majority of thrombocytopenic patients in resource poor setting.

Keywords Platelet concentrates · Buffy coat method · Plateletpheresis

Introduction

Blood Banks have the responsibility to provide blood components of good quality so as to ensure a safe and effective transfusion. Preparation of blood components and their quality control differ in many aspects from drug manufacture as each blood component unit is a specific batch and it is not possible to check stability, efficiency, safety and sterility of each individual unit. Platelet concentrates (PCs) are manufactured by platelet rich plasma platelet concentrate (PRP-PC) method, Buffy coat poor-platelet concentrate (BC-PC) method (from whole blood) and by apheresis derived platelet concentrate (Apheresis-PC) (with the help of an automated cell separator). It has been shown in various studies that BC-PC is better method of PCs than PRP method [1]. The in vitro platelet quantity and quality can be assessed by swirling, volume, platelet count, WBC count and pH in the product and by various other biochemical parameters (Table 1) [2].

The BC-PC by Top & Bottom approach allows a reduction in leukocyte contamination of blood components—which benefits the patient by reducing the incidence of febrile non-hemolytic transfusion reactions

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Table 1 Quality control parameters for BC-PC and Apheresis PC (DGHS Technical Manual 2nd Edition)

Parameters	Quality requirement for BC-PC	Quality requirement for Apheresis-PC	Frequency of quality control	Unit tested in this study
Swirling	Present	Present	All units	200 BC-PC and 200 Apheresis-PC units
Volume of PC unit (ml)	70–90 ml	200–300 ml	All units	200 BC-PC and 200 Apheresis-PC units
Platelet count/unit	$6-9 \times 10^{10}$ in 75 % of units tested	$>3-7 \times 10^{11}$ in 75 % of units tested	Monthly	200 BC-PC and 200 Apheresis-PC units
WBC count/unit	$5.5 \times 10^7-5 \times 10^8$	$<5 \times 10^6$	Monthly	50 units from each BC-PC and Apheresis-PC
pH	>6.0 at the end of maximum days of storage in 100 % units tested	>6.0 at the end of maximum days of storage in 100 % units tested	Monthly	50 units from each BC-PC and Apheresis-PC

(FNHTR). Presently apheresis technology has made huge impact on supply of platelets. The advantage of Apheresis-PC is higher yield & adequate potency from a single donation i.e. one Apheresis-PC is equivalent to four to six BC-PC units. The leukocyte contamination of Apheresis-PC products is as low as that achieved by leucofiltration. The procedure takes approximately 60–90 min. Apart from decreasing FNHTR Apheresis-PC also minimizes Cytomegalovirus transmission and development of HLA alloimmunization. However it is available, at a relatively higher cost.

Is plateletpheresis an answer to all PCs demand? This is a matter of debate. Our blood centre is a part of an urban tertiary care teaching hospital. At our centre the turnover of PCs prepared from whole blood is 10,000 annually, out of which the ratio between PRP-PC method and BC-PC method is around 80:20. This caters to the routine platelet requirement of the hospital. We also have annual production of approximately 1,000 Apheresis-PC to cater for specially indicated patients. Many blood centers in country don't have such costly apheresis technology and much needed expertise. These centers rely heavily on the platelet production from whole blood. At the same time, the BC-PC has been shown to be comparable in many aspects to Apheresis-PC [3]. It is available at much lower cost in plenty at these centers with an added advantage of some logistics issues [1].

We conducted this study with the aim to compare the quality of platelet concentrates (PCs) prepared by BC-PC and Apheresis-PC based on the quality recommendations given by DGHS technical Manual, for the production and storage of platelet concentrate [2].

Materials and Methods

This is a one year prospective study conducted in the Department of Immunohematology and Blood Transfusion

between Oct 2011 and July 2012. A total of 200 BC-PC and 200 Apheresis-PC product were assessed for their in vitro quality, by observing swirling, volume of PC, platelet counts/unit, residual WBC count/unit and pH, to see if they satisfy the recommended quality criteria by DGHS technical Manual [2]. Data was analyzed using appropriate statistical technique like Chi square test and unpaired *t* test.

A proper medical history was taken and the donors were examined for their general health and well being. Donors were provided about the information regarding whole blood donation and apheresis donation and possible adverse effects during and after donation. It was ensured that no anti-platelet medication was taken by donors that irreversibly inhibit platelet function. All donors gave their written informed consent. Their vital parameters were recorded. Skin for the phlebotomy site was inspected. Emphasis was given on the correct method of arm disinfection as the main source of bacterial contamination in PCs is the donor skin flora [4, 5]. Venous access was an important consideration in apheresis donors due to long duration of procedure. The review of the two methods is as follows:

Whole Blood Derived Platelet Production by BC-PC Method

Donor blood (450 ± 45 mL) was collected into the Quaduple system of blood bags with citrate, phosphate and dextrose (CPD) anticoagulant solution (63 ml) in the primary bag and 100 mL of saline, adenine, glucose and mannitol (SAGM) additive solution for PRBCs in one satellite bag. The initial 10 ml of blood was diverted into the diversion pouch provided with the blood bag collection set. With sufficient flow, the duration of a whole blood collection was kept between 4 and 8 min as prolonged duration of flow during donation leads to consumption of platelets. Whole blood was stored at 22 ± 2 °C using

insulated transport box. Blood units were processed within 8 h.

Whole blood in CPD-SAGM, Quadruple bags was centrifuged in Cryofuge with “hard spin” centrifugation at 3,950 rpm for 9 min at 22 °C with acceleration and deceleration curves of 8 and 5 respectively. The centrifuged blood was separated into distinct layers in automated Optipress II by applying protocol 1 (Baxter, Fenwal Division, Deerfield, USA). The resulting top layer, middle layer and bottom layer were consisted of platelet poor supernatant plasma, the Buffy coat and packed red cells respectively.

Platelet poor supernatant was expressed into top FFP satellite bag. The packed red cells were transferred to the bottom PRBC bag containing SAGM. The bags containing red cells and plasma were then separated. PRBC was placed at 4 °C in cold room and platelet poor plasma was transferred into a –40 °C deep freezer as FFP.

The Buffy coat with the plasma was hung at a height to settle for 40 min. A thorough but gentle mixing of BC was done before putting the BC for second centrifugation. BC bags were centrifuged at light spin” centrifugation at 1,050 rpm for 5 min at 22 °C, with acceleration and deceleration curves of 7 and 4 respectively, along with one empty satellite bag.

There was a distinct interface between residual cells and platelet rich plasma after centrifugation. The supernatant platelet rich plasma was expressed into satellite platelet storage bag applying protocol 2 on Optipress II. The residual Buffy coat remained in the primary bag. After appropriate volume (70–90 ml) was collected air bubbles were completely removed from the platelet concentrate before sealing the BC-PC bag. Platelet concentrate bags were labeled and detached from residual Buffy coat bag. The platelet concentrate bags were left stationary, with the label side down, at room temperature (temperature controlled environment of 20–24 °C) for approximately one hour and then transferred to flatbed platelet incubator cum agitator and stored at 22 ± 2 °C for 5 days.

Automated Apheresis Collection for Apheresis-PC

Plateletpheresis donors met the same donor selection criteria as allogeneic blood donors. In addition, the donors were confirmed to have platelet count $>150 \times 10^3/\mu\text{L}$ and hematocrit of 38 %. We used Amicus (Fenwal) single venous access, continuous flow, automated cell separator. Donors were offered oral calcium (300 mg) before commencement of procedures to prevent the symptoms and signs of hypocalcaemia.

The Amicus cell separator uses centrifugal force and a double compartment belt wrapped around a spool to separate the platelets. The platelets accumulated in the collection

chamber are transferred with plasma to the final collection bags at the end of the procedure. It processes blood by continuous flow centrifugation, with an uninterrupted separation and return circuit. The process of cell separation during centrifugation also isolates leukocytes for “process leukoreduction” during the apheresis collection.

Sampling of PCs for QC parameters was done aseptically as described by AABB technical manual 17th edition, without compromising the sterility of the component [6]. Determination of, swirling, volume, platelet count and WBC count, was performed on the same day (D1). pH testing was performed on the last day (D5) or day of issue whichever was earlier. None of the units was wasted due to expiry of shelf life.

Swirling

Swirling was assessed by inspection against bright background and graded according to methodology of Ravindra P Singh et al. [3]. The swirling was evaluated by examining the units against light and scored as:

Score 0: Homogeneous turbid and is not changed with pressure.

Score 1: Homogeneous swirling only in some part of the bag and is not clear.

Score 2: Clear homogeneous swirling in all part of the bag.

Score 3: Very clear homogeneous swirling in all part of the bag.

Volume Determination

Volume of the unit content was calculated with help of platelet concentrate specific gravity i.e. 1.03

Volume of PC (ml)

$$= \frac{\text{Wt of full PC bag} - \text{Wt of empty PC bag}}{\text{specific gravity of PC}}$$

Determination of Platelet Count Per Bag

Determination of platelet counts in PC samples was performed on Sysmex KX 21 hematoanalyser. The platelet count per bag was calculated by the formula:

$$= \text{Platelet count per } \mu\text{L} \times 10^3 \\ \times \text{volume of the PC (ml)}$$

WBC Count

WBC count in the PCs bag was performed on 50 randomly selected units. This number was considered after consultation with the biostatistician. This was because the procedure of WBC counting was cumbersome manually by

Nageotte chamber & hence 50 was considered to be an adequate number for the comparison of WBC count by this labour intensive method. The BC-PC product can be measured on automated hematology analyzer, sysmex 21, as the BC-PC products are only 1–2 log reduced, and are within measureable range of analyser. It works on the principle of impedance or light scattering properties of cells suspended in a medium. The limit for accuracy of this instrument is 100 cell/ μL and thus it cannot be used for QC for apheresis products. Large volume (50 μL) Nageotte hemocytometer was employed for Apheresis-PC product to count WBC contamination. WBC count for Apheresis-PC was done manually using Nageotte hemocytometer as follows, since expected WBC count is below the measurable range of cell counter [7].

$$\text{WBC count in Nageotte hemocytometer (WBC}/\mu\text{L}) \\ = (\text{cells counted}/50) \times 5$$

where, 50 μL is the volume and 5 is the dilution factor. WBC contamination for BC-PC was found from analyzer, WBC calculation in PC bag = WBC concentration/ $\mu\text{L} \times 10^3 \times \text{volume of PC (ml)}$.

pH Evaluation

pH was determined on 50 randomly selected units by the use of an digital pH meter (Desibel). This number was considered after consultation with the biostatistician. PCs were never held back till 5th day for the sake of pH study only, so the entire 200 units were not available for pH measurement till day 5. Hence 50 PCs were selected for pH estimation since this number would actually be available for pH detection. Further pH analysis was carried out by an electrode based method, which is more labour intensive than the strip method. The pH was evaluated at the end of the maximum day of storage or on the day of issue whichever was earlier. Each time before use, the pH meter was calibrated with pH indicator solution. First the pH meter was calibrated with solution of pH 7.0 and counter checked by putting the electrode in a solution of pH 4.0. After calibration pH bulb was put in PC sample in glass beaker. Samples were measured at room temperature immediately upon pouring into glass beaker.

Results

Swirling in PC Units (Table 2)

Swirling was observed in every individual unit and scored as score 0–3 according to subjective observation. Swirling with score 3 was observed in 52.5 and 88.5 % of units while score 2 swirling was noticed in 47.5 and 11.5 % of

BC-PC and Apheresis-PC units respectively. No unit had scored 1 and below. Chi-square test shows that there is a significant difference in proportion of PCs with higher swirling score between the two methods. Apheresis-PC units showed better swirling than BC-PC units ($P < 0.05$).

Volume in Two PC Methods (Table 3)

Our results show mean volume collected in BC-PC units as 74.33 ± 9.618 ml whereas mean volume of Apheresis-PC units is 269.13 ± 24.135 ml of plasma. The volume ranges from 44.66 to 94.10 ml in BC-PC and 195–376 ml in Apheresis-PC. Apheresis-PC units met the QC with 94.5 % of units meeting QC parameters while only 65.5 % of BC-PC units were able to meet the QC volume. Coefficient of variation (C.V.) of BC-PC is higher thereby showing more variation in the units adhering to the volume parameter. Chi-square test shows there is a significant difference in proportion of units satisfying the required volume QC between the methods ($P < 0.05$). Apheresis-PC showed better adherence to the required QC parameter for volume.

Platelet Count Per Unit (Table 3)

The mean platelet count of 200 BC-PC units was $8.759 \pm 2.898 \times 10^{10}$ (mean $\pm$ SD) per unit and ranged from 1.55 to 16.95×10^{10} per unit. The mean platelet count of Apheresis-PC units was $3.926 \pm 0.746 \times 10^{11}$ (mean $\pm$ SD) per unit and ranged from 1.09 to 8.58×10^{11} per unit. Ninety percent i.e. 180 of BC-PC units had platelet counts $>5.5 \times 10^{10}$ per unit, and 187 (93.5 %) of Apheresis-PC units met the desired criteria of 3×10^{11} /unit. (Both methods showed more than required 75 % units qualifying the QC parameter). C.V. of BC-PC is higher than that of Apheresis-PC showing variation in units adhering to the platelet count parameter. Chi square test reveals no significant difference in proportion of units satisfying the required platelet count QC between the two methods ($P = 0.203$).

WBC Contamination in Two PCs (Table 3)

A total of 50 units each were analysed for WBC count at day 1. Mean of the residual WBC per bag of Apheresis-PC product was $3.140 \pm 1.314 \times 10^6$ whereas it was $2.928 \pm 1.204 \times 10^7$ in BC-PC units. WBC contamination

Table 2 Scores for swirling in two methods of PC preparation

Score	BC-PC (n = 200)	Apheresis-PC (n = 200)
3	105 (52.5 %)	177 (88.5 %)
2	95 (47.5 %)	23 (11.5 %)
1	Nil	Nil
0	Nil	Nil

Table 3 Comparison for volume per unit, platelet count per unit, residual WBC contamination and pH in two methods of PC preparation

		Mean $\pm$ SD	Range	% of units satisfying QC	Coefficient of variation	P value
Volume (ml)	BC-PC (n = 200)	74.33 $\pm$ 9.618 ml	44.66–94.10 ml	131 (65.5 %)	12.93 %	P < 0.05 (Chi-square test)
	Apheresis-PC (n = 200)	269.13 $\pm$ 24.135 ml	195–376 ml	189 (94.5 %)	8.96 %	
Platelet count ($\times 10^6$)	BC-PC (n = 200)	8.759 $\pm$ 2.898 $\times 10^{10}$ /unit	1.55–16.95 $\times 10^{10}$ /unit	180 (90 %)	33.0 %	P = 0.203 (Chi-square test)
	Apheresis-PC (n = 200)	3.926 $\pm$ 0.746 $\times 10^{11}$ /unit	1.09–8.58 $\times 10^{11}$ /unit	187 (93.5 %)	19 %	
WBC ($\times 10^6$)	BC-PC (n = 50)	2.928 $\pm$ 1.204 $\times 10^7$ /unit	1.145–6.679 $\times 10^7$ /unit	47 (94 %)	41.12 %	P = 0.617 (Chi-square test)
	Apheresis -PC (n = 50)	3.140 $\pm$ 1.314 $\times 10^6$ /unit	0.289–6.825 $\times 10^6$ /unit	49 (98 %)	41.84 %	
pH	BC-PC (n = 50)	6.876 $\pm$ 0.385	6.2–7.4	50 (100 %)	5.59 %	P < 0.05 (unpaired <i>t</i> test)
	Apheresis-PC (n = 50)	7.078 $\pm$ 0.375	6.3–7.4	50 (100 %)	5.29 %	

of Apheresis-PC products was ranging from 0.2892 to 6.825×10^6 per unit whereas for BC-PC products it was $1.145\text{--}6.679 \times 10^7$ per unit. Ninety-eight percent of the Apheresis-PC products contained less than 5×10^6 WBC/unit where as 94 % BC-PC products contained less than 5×10^7 WBC/unit. C.V. shows no difference between two preparation methods. Chi square test shows no significant difference in proportion of units satisfying WBC contamination QC, between the two methods (P = 0.617).

pH in PC Units (Table 3)

A total of 50 units each for both groups were analyzed for pH changes at either on day 5 or on day of issue. The mean pH was 6.876 ± 0.385 (mean $\pm$ SD) and 7.078 ± 0.375 for BC-PC and apheresis PC respectively using unpaired '*t*' test. A statistically significant difference was observed for the pH between the two types of platelet concentrate preparation methods. Apheresis -PC showed better adherence to the physiological pH values.

Final Scoring

Final scoring (Table 4) was done in consultation with biostatistician, on the basis of parameters (i.e., swirling, volume, platelet count, WBC count and pH changes) taken for quality control evaluation for PCs units. Score was given according to number of parameters fulfilled by each units; for example, score 5 or 4 was given to those units which fulfilled 5 or 4 recommended quality control parameters respectively. WBC counting and pH evaluation was done in selected 50 units. Scoring for the two different groups was given i.e. for the PCs which were tested with 3 QC criteria and PCs which were tested with 5 QC criteria. A considerably larger proportion of Apheresis-PC units achieved a higher final score, both when 3 and 5 QC parameters were compared.

Table 4 Shows the scores for two methods for units evaluated for various parameters (swirling, volume per unit, platelet count, pH and WBC contamination)

Final scores	BC-PC n/N	(%)	Apheresis-PC n/N	(%)
5	26/50	52	45/50	90
4	17/50	34	4/50	8
3	102/200	51	132/200	66
2	50/200	25	19/200	9.5
1	5/200	2.5	0/200	0

(Only 50 units from each groups were evaluated for pH and WBC contamination, and for other three parameters 200 units were evaluated from each group; n/N)

Discussion

The selection of preparation methods of PCs production should be based on availability of resources and efficacy. As a result of the different preparation methods there is substantial variability of the QC of products with regard to platelet content, residual leukocyte count etc. Sampling for QC provides early assurance that production is within specification. Adequate QC parameters give assurance that the processing system in use maintains the integrity of a closed system. Non adherence to QC parameters should be viewed as a potential processing problem and needs thorough investigation. In United States the platelet supply is mainly by Apheresis-PC and PRP-PC methods. In Europe there is approximately 50:50 split between the use of BC-PC and Apheresis-PCs. In Canada 70 % of PCs are derived from whole blood donation Denmark, Finland and the Netherlands prepare 85–95 % of their concentration by the BC-PC method [1]. Surprisingly there are very few study available which compare QCs of RDP units (without pooling) with SDP units.

Swirling

Most of the QC assays involve sampling. These assays require special laboratory devices and dedicated personnel, and cannot be performed on all PCs. Swirling is easily evaluated without any instrumentation. Discoid platelets when viewed through a light source manifest the “swirling” phenomenon. Evaluation of swirling is a simple procedure and is useful for routine quality control of each individual PC on a large scale. However, this macroscopic measure may be too insensitive a measure for lesser degrees of irreversible platelet damage occurring in fewer numbers of platelets in the PC. The absence of swirling in PC is highly predictive of poor post-transfusion platelet count increments and increased risk of a transfusion reaction [8]. Absence of swirling is consistent with accumulation of lactic acid, decrease in pH, and loss of platelet discoid shape when there is a lack of oxygen during platelet storage. In our study swirling scores findings were similar to those obtained in a study carried out by Ravindra P Singh et al. [3].

Volume

AABB has not mentioned about the volume limit of BC-PC and Apheresis-PC. DGHS recommendation is 70–90 ml for BC-PC and 200–300 ml for Apheresis-PC [2].

Plasma volume for platelet resuspension must be adequate to enable appropriate platelet metabolism and to preserve pH > 6.2 throughout the storage period. A probable cause for the reduction in viability associated with reduced pH and increased lactate production may be that a reduction in the suspending volume results in increased container surface-to-PC volume ratio, which may lead to more frequent platelet container wall interactions, with a risk of increased platelet activation or stimulation [9]. We found significant difference in proportion of units satisfying the required volume QC between the two methods ($P < 0.05$, Chi square test). Apheresis-PC showed better adherence to the required QC parameter for volume. Higher volume does not have any deleterious effect on platelet function and maintains the pH throughout the storage period by its buffering action. The mean volume BC-PCs are comparable to those reported by Fijnheer et al. [10]. However, the Coefficient of variation in BC-PC units is more than that of Apheresis-PC thereby implying that more standardization is required in their preparation.

Platelet Count

The preparation methods must yield at least 5.5×10^{10} platelets per unit in at least 75 % of the units by BC-PC method and at least 3×10^{11} platelets per unit in at least 90 % of the Apheresis-derived platelets. Although a higher

number of Apheresis-PC units met the desired quality control for platelet count, there was no significant difference in proportion of units satisfying the required platelet count QC between the two methods ($P = 0.203$, Chi square test). Results of PCs volume per units from our study are comparable to the study done by Rajendra et al. [3].

WBC Contamination

BC-PC method of platelet provides 1–2 log reduction by virtue of removal of Buffy coat. Apheresis-PC products are effectively leucoreduced by 3–4 log. In our study we could achieve a good leucoreduction for both, BC-PC and Apheresis-PC units against the respective set QC limits. Leucocytes found in blood components are responsible for the majority of transfusion reactions including alloimmunization to leukocyte antigens, febrile non-hemolytic transfusion reaction, refractoriness to platelet transfusion, severe pulmonary dysfunction, graft versus host disease, the transmission of cytomegalovirus. WBCs in PC also have a detrimental effect on the storage medium, resulting in a significant drop in pH, increase in glucose consumption, lactic acid production and poor platelet morphology during storage. As a result, high concentration of leukocytes in PCs, significantly affects platelet 5 days storage. Platelet preparation and storage may affect release of leukocyte- and platelet-derived bioactive substances. An increased extracellular concentration of histamine in BC-PC as compared to Apheresis-PC was shown in some studies [11, 12]. Results of residual WBC contamination in our study are comparable to the study conducted by Rajendra P Singh et al. [3].

pH

The majority of fresh, un-stimulated platelets are discoid with few projections at pH 7.4. During storage of PCs a gradual disc-to-sphere transformation occurs. If pH falls below 6.8 levels, platelet may swell due to influx of extracellular fluid. This swelling reaches its maximum at a pH of 6.0. The changes occurring below pH 6.0 are not reversible. The resulting platelets are not suitable for transfusion. The platelet storage conditions, such as plasma volume, agitation, and temperature, must be optimized to maintain an adequate pH of greater than or equal to 6.2 in 100 % of the units tested at the end of 5 days storage period. We measured pH at storage 22 ± 2 °C temperature as studies have proved that temperature has its impact on pH values [13]. Our results for pH on 50 units from each group reflected good storage conditions. Although statistically significant difference was observed for pH between two types of PC preparation methods ($P < 0.05$, unpaired ‘*t*’ test), all units showed pH within QC criteria. Apheresis-PC showed better adherence to the physiological pH values. This could be due to less

activated platelets in apheresis PC, and ongoing residual WBC metabolism and higher platelet activation due to dual centrifugation in BC-PC.

Each type of PC has advantages and disadvantages. Apheresis-PCs have advantage of providing product of lesser RBC and WBC contamination and limited exposure to donor as the product is derived from a single donor. One Apheresis-PC unit has high content of platelet which is equivalent to four to six BC-PC units. Apheresis-PC has better in vitro QC parameters and BC-PCs might exhibit greater in vitro storage lesion. Apheresis-PC production is more expensive as compared to equivalent 4–6 units of BC-PC as the expenditure required for plateletpheresis is added expenditure for instruments, disposable kits and skilled technician. There are no significant differences in FNHTR and HLA/HPA alloimmunization provided both the units are leucoreduced. However the Apheresis-PC show better efficacy in HLA/HPA allo-sensitized and refractory patients as compared to BC-PC products as HLA/HPA matched donor products can be prepared.

Summary

A higher swirling score and volumes in narrow range were achieved in Apheresis-PC and this was attributable to extensive automation of procedure and uniformity of the continuous centrifugation. Low swirling score in BC-PC can be attributed to higher platelet activation due to dual centrifugation step. BC-PC showed a wider range of volume probably due to minor variations in procedure, since complete automation was not involved. This suggests that much more standardization is required for preparation of PC from BC-PC method.

A slightly higher number of Apheresis-PC units achieved the QC limit of platelet count as compared to BC-PC units. This could be due to the better efficiency of the cell separator due to complete automation. Strict standard operating procedures (SOPs) should be formulated and followed to streamline the procedure so that required platelet counts are achieved in more numbers of BC-PC as well. Adequate leucoreduction and recommended pH were achieved in PCs from both methods as required by QC. Leucoreduction was close to the ideal i.e. $<5 \times 10^6$ by apheresis, owing to the inherent methodology of procedure which incorporates in process leucoreduction. In this study, the BC-PCs have been found to be adhering lesser to QC parameters as far as swirling, volume and pH are concerned, but do not lag behind much.

One Apheresis-PC unit costs approximately five to six times the cost of an equivalent 6 BC-PC units. However in our resource poor setting BC-PC which is more readily

available can be used effectively in the majority of thrombocytopenic patients where platelet transfusion is indicated. On the other hand scarcely available Apheresis-PC should be reserved for the more deserving multi-transfused immuno-compromised patients and when HLA-matched/HPA matched/cross matched platelet transfusions are indicated. This will ensure optimum use of both products, and will go a long way in ensuring high quality patient care.

This study further re-enforces the fact that in places where organisational and its financial set-up put constraints on preparation of Apheresis-platelets, BC-PCs provide an equally comparable alternative. In the meantime, further research can be directed to enhance the product quality derived from Buffy coat method by further refinement of preparation protocols.

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