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ORIGINAL ARTICLE

Therapeutic efficacy of different types of platelet concentrates in thrombocytopenic patients

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Abstract

Background Platelet Rich Plasma-Platelet concentrate (PRP-PC), Buffy Coat poor-platelet concentrate (BCPC), and Apheresis – PC were prepared and their therapeutic efficacy were assessed in thrombocytopenic patients.

Study design and methods PRP-PC and BC-PC were prepared from whole blood and Apheresis-PC by automated cell separator. The post transfusion efficacy of transfused platelets was assessed at 1 hour and 20 hours by corrected count increment (CCI) and percentage recovery (PR).

Results A total of 60 patients' (20 each for PRP-PC, BC-PC and Apheresis-PC) were enrolled in this study. Forty one patients received therapeutic and nineteen received prophylactic transfusion support. Patients with aplastic anemia 43% (25/60) and acute leukemia 38% (23/60) formed a majority of study population. Platelet dosage of patients' received PRP-PC, BC-PC and apheresis-PC were 2.4±0.82 × 1011 (mean±SD), 2.2±0.83 × 1011 (mean±SD) and 4.14±1.82 × 1011 (mean±SD) and ranged from 1.16–4.11 × 1011, 1.04–4.20 × 1011 and 1.22–8.90 × 1011 respectively. There was significantly increase in inter-transfusion interval with Apheresis-PC than with PRP-PC and BC-PC recipients [(Mean±S.D.), 4.7±1.33 days Vs 2.7±0.82 days Vs 2.5±0.7 days respectively] ($p < 0.05$).

Conclusions Patients transfused with apheresis-PC had received higher platelet dosage than PRP-PC and BC-PC and this difference was statistically significant ($p < 0.001$). The post transfusion platelet counts and increments at 1 hour and 20 hours were significantly higher with apheresis-PC than PRP-PC and BC-PC ($p < 0.001$). However, the corrected count increment (CCI) and percentage recovery (PR) in all three groups were comparable. There was significantly increase in inter-transfusion interval with apheresis-PC than PRPPC and BC-PC ($p < 0.05$).

Keywords Random donor platelets · Buffy coat poor-platelet concentrate · Platelet Rich Plasma-Platelet concentrate · Thrombocytopenic patients

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List of Abbreviations

RDP - Random donor platelets
SDP - single donor platelets
PRP-PC - Platelet Rich Plasma-Platelet concentrate
BC-PC - Buffy coat poor-platelet concentrate
PC - platelet concentrate
CCI - corrected count increment
PR - percentage recovery.

Introduction

Platelet transfusions are the primary therapy for thrombocytopenia due to various causes. Thrombocytopenia may be due to qualitative defect, i.e. defect in platelet function or

quantitative defect, i.e. decreased platelet count which can be seen in various hemato-oncological patients either due to primary disease or chemotherapy.

The basic principle behind preparation of components from whole blood is that, each component has its specific gravity and by applying centrifugation, each component is separated and removed, thus allowing the transfusion of desired component according to the need of the patient.

The recommended shelf life of platelet concentrates in presently available platelet storage bag is 5 days at 22±2°C with continuous agitation. The platelets undergo various storage changes starting from collection, processing to storage and the underlying conditions within the patients, which may affect the therapeutic benefit to the recipient [1].

The in vivo platelet quality can be assessed by using corrected count increment (CCI) and percentage recovery (PR) at 1 hour and 20 hours post transfusion which accesses the functional platelets in circulation after transfusion. If the CCI at 1 hr and 20 hour is <7500 platelets/ μL/m^2 and < 4500 platelet/μL/m^2 and PR at 1 hour and 20 hour <30% and <20% respectively on two consecutive occasions it indicates platelet transfusion refractoriness [2].

In this study we have analyzed the quality of different platelet concentrates prepared by different methods as per the quality norms recommended and assessed the therapeutic benefits of each of these platelet concentrates in thrombocytopenic patients.

Material and methods

This study was conducted during the period from January-2003 to December-2003 in the departments of Transfusion Medicine, Hematology and lab. and Internal Medicine of the institute, after obtaining clearance from the ethics committee of the institute.

During this period, total number of 44,069 whole blood units were collected, and 7,167 random donor platelets [PRP-PC-3,081(6.9%) and BC-PC-810(1.8%)] were prepared. Whole blood was collected in 450-ml bag containing 63 ml of CPDA1 anticoagulant, kept at room temperature (20–24°C) and PRP-PC was prepared within 6–8 hours of collection.

Single donor platelets were prepared from ninety-eight (98) donors by continuous flow, double venous access, automated cell separator – CS3000 ® plus, Baxter, Fenwal division, Deerfield, 14 60015, USA.

The study group Patients with mainly hematological disorders with severe thrombocytopenia (i.e., platelet count < 20000/μl), who required prophylactic or therapeutic platelet transfusion were subjects of the study. Twenty patients each were evaluated for therapeutic efficacy of platelet rich plasma–platelet concentrate (PRP-PC), buffy coat poor–platelet concentrate (BC-PC) and apheresis PC.

Exclusion criteria Patients with high-grade fever (≥102°F), splenomegaly (moderate to massive), idiopathic thrombocytopenic purpura (ITP) and thrombotic thrombocytopenic purpura (TTP) were excluded, as these conditions are known to be associated with unduly increased utilization of platelets.

Sample collection Two to three ml of sample from platelet concentrates either SDP or RDP was collected aseptically in plain vial prior to the transfusion to the patients. Two to three ml of patient's blood was collected in EDTA at three different times, first sample 1–2 hours prior to the transfusion after a requisition was received for platelet transfusion and rest of the two samples were collected at 1 hour and 20 hours post-transfusion respectively. Platelet counting was done by automated cell counter (MS 4 Melet Schloesing, laboratories, France).

In vivo efficacy of transfused platelets was assessed by calculating the corrected count increment (CCI) and percentage recovery (PR) at 1 hour and 20 hours of transfusion respectively.

(A) Corrected Count Increment (CCI) [3]

$$CCI = \frac{\text{Platelet increment}/\mu l \times BSA\ (m^2) \times 10^{11}}{\text{No. of platelets transfused}} = \text{Platelets}/\mu l/m^2$$

Platelet increment = Post transfusion platelet count – Pre transfusion platelet count.

Estimation of BSA (Body surface area): [4]

$$BSA\ (m^2) = \frac{\sqrt{\text{Height (Cm.)} \times \text{Weight (Kg.)}}}{3600} \quad \text{OR}$$

$$BSA\ (m^2) = \frac{\sqrt{\text{Height (in.)} \times \text{Weight (lb.)}}}{3131}$$

(B) Percentage Recovery (PR) [2]

$$PR\ (\%) = \frac{\text{Platelet increment } 10^9/L \times \text{blood volume (BV)} \times 100}{10^{11} \text{ transfused platelets}}$$

Blood volume (BV) was calculated according to the following formulae [5] –

Blood Volume (ml) for male = Wt. (kg) × 69 ml/kg

Blood Volume (ml) for female = Wt. (kg) × 65 ml/kg

Statistical analysis All data were expressed as mean±SD. We performed statistical comparison by using't'-test for multiple groups. A probability of $p<0.05$ (two sided) was used to reject null hypothesis.

Observation and results

In sixty patients (twenty each for PRP-PC, BC-PC and Apheresis – PC) 64 units, 62 unit and 20 units of PRP-PC, BC-PC and Apheresis – PC respectively were transfused.

Most of the patients had underlying hemato-oncological diseases (n=57) while rest 3 patients had thrombocytopenia with viral fever (n=2) and diabetes mellitus (n=1). Patients with aplastic anemia 43%(25/60) and acute leukemia (ALL, AML and undifferentiated) 38%(23/60) formed a majority of the study population. This was followed by chronic leukemia (CLL, CML) 5%(3/60), thrombocytopenia (with diabetes mellitus and viral fever) 5%(3/60), pancytopenia (unclassified) 3%(2/60), myelodysplastic syndrome (MDS) 3%(2/60), myelofibrosis 1.5%(1/60) and multiple myeloma 1.5%(1/60). Of the patients who received PRP-PC (n=20), majority of them had aplastic anemia (n=11) and acute leukemia (n=6), followed by chronic leukemia, unclassified pancytopenia and myelodysplastic syndrome (n=1) respectively. The patients who received BC-PC (n=20) had underlying acute leukemia (n=9) and aplastic anemia (n=5), followed by chronic leukemia and thrombocytopenia with viral fever (n=2) and unclassified pancytopenia and myelodysplastic syndrome (n=1) respectively. The patients who received Apheresis-PC (n=20), had underlying aplastic anemia (n=9) and acute leukemia (n=8), followed by thrombocytopenia with diabetes mellitus, myelofibrosis and multiple myeloma (n=1) respectively (Table 1).

Out of 60 patients enrolled in this study, 41(68.3%) presented with signs/symptoms of bleed. The maximum number of patients presented with complaints of minor gum bleeds 58.5%(24/41) followed by petechial rashes17.1%(7/41), epistaxis 14.7%(6/41), subconjunctival hemorrhage 4.9%(2/41), menorrhagia 2.4%(1/41) and altered sensorium 2.4%(1/41) (Table 2).

Forty one (68.3%) patients presenting with signs and symptoms of bleed required therapeutic platelet transfusion support. Two of these 41 patients had pre-transfusion platelet count >20,000/ul (i.e., one had pre-transfusion platelet count 35,000/ul and presented with acute sub dural hematoma (SDH) which was planned for evacuation, while the other patient had pre-transfusion platelet count 30,000/ul and presented with epistaxis due to intranasal mucormycosis infection). Nineteen patients (31.7%) did not have any signs/symptoms of bleed and required prophylactic platelet transfusion support because of low platelet count. Two of these19 patients had pre-transfusion platelet count >20,000/ul (i.e., one had pre-transfusion platelet count 35,000/ul and was planned for amphotericin therapy, while other pa-

Table 1 Underlying diseases in patients requiring platelet transfusion

Diagnosis	Patients with PRP-PC transfusion (n=20)	Patients with BC-PC transfusion (n=20)	Patients with Apheresis-PC transfusion (n=20)	Total	Percentage
Aplastic anemia	11	5	9	25	43
Acute leukemia (ALL, AML, undifferentiated)	6	9	8	23	38
Chronic leukemia (CLL, CML)	1	2	–	3	5
Thrombocytopenia	–	2*	1†	3	5
Pancytopenia (unclassified)	1	1	–	2	3
Myelodysplastic syndrome (MDS)	1	1	–	2	3
Myelofibrosis	–	–	1	1	1.5
Multiple myeloma	–	–	1	1	1.5

*Thrombocytopenia with viral fever

†Thrombocytopenia with diabetes mellitus

Table 2 Signs and symptoms of bleeding in patients receiving platelet concentrates (n=41)

Signs and symptoms	Total (n=41)	Percentage
Gum bleed	24	58.5
Petechial rashes	7	17.1
Epistaxis	6	14.7
Subconjunctival hemorrhage	2	4.9
Menorrhagia	1	2.4
Altered sensorium	1	2.4

tient had pre-transfusion platelet count 68,000/ul and was planned for dental extraction).

Platelet dose Ideally the platelet dose to be transfused needs to be calculated according to the weight of the patient. The mean weight of the patients who received PRP-PC (n=20), BC-PC (n=20) and Apheresis-PC (n=20) was 51.6±10.3 kg, 53.0±14.2 kg and 61.5±13.7 kg (mean±SD) and ranged from 32–76 kg, 25–80 kg, and 38–85 kg respectively. The dose of the PRP-PC/BC-PC was calculated by 10-ml/kg-body weight of the patients [6]. The optimal dose calculated from the above equation was approximately 5 to 8 PRP-PC/BC-PC units per patients. However ABO blood group-wise platelet inventory is not always adequate, due to short shelf life of platelet concentrates. We were able to provide approximately 3 to 4 units of PRP-PC/BC-PC per patient. Optimal dose of Apheresis-PC is approximately 3×10^{11} and thus with Apheresis-PC, adequate platelet dose could be provided to majority of the patients in the group. The mean platelet dosage was thus significantly higher than both PRP-PC and BC-PC (P<0.01).

On analyzing the parameters in total numbers of patients for each platelet preparation, it was observed that the dosage available from Apheresis-PC was significantly higher [apheresis-PC Vs PRP-PC (p<0.0008) and apheresis-PC Vs BC-PC (p<0.002)] (Table 3).

The overall platelet counts and increments of the three groups are shown in details (Table 4 and Fig. 1).

The post transfusion platelet counts and the increments at 1 hour and 20 hours were significantly higher with Apheresis-PC transfusion as compared to transfusions with PRP-PC and BC-PC. However, the CCI and PR in all the three groups were comparable.

Disscussion

The issue of prophylactic versus therapeutic platelet transfusion therapy arises in the management of any patient with severe non-immunologically mediated thrombocytopenia [7]. Primary goal of prophylactic platelet transfusion therapy is to decrease the incidence and severity of bleeding during the periods of severe thrombocytopenia. This practice is summarized in a 1986 consensus conference statement: “the patient with severe thrombocytopenia may

Table 3 Platelet dosage of platelet concentrates

	Platelet dosage		
	Patients transfused PRP-PC (n=20)	Patients transfused BC-PC (n=20)	Patients transfused Apheresis-PC (n=20)
Mean ± SD	$2.4\pm0.82 \times 10^{11}$	$2.2\pm0.83 \times 10^{11}$	$4.14\pm1.82 \times 10^{11}$
Range	$1.16–4.11 \times 10^{11}$	$1.04–4.20 \times 10^{11}$	$1.22–8.9 \times 10^{11}$

P value- Apheresis-PC vs PRP-PC – 0.0008- Significant

Apheresis-PC vs BC-PC – 0.002 - Significant

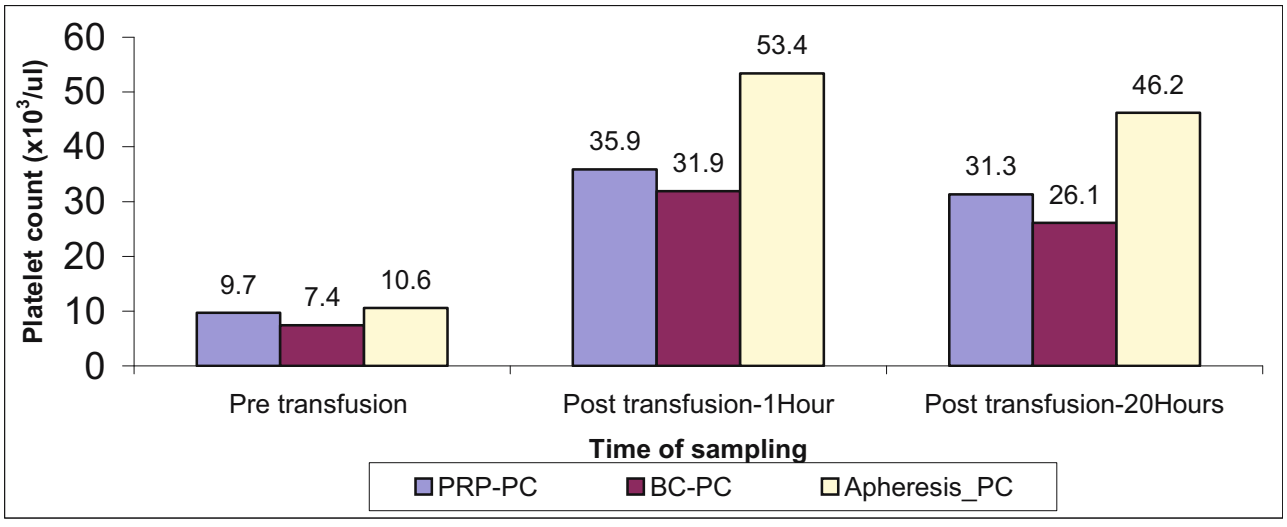

Fig. 1 Pre transfusion and post transfusion (at 1 hour and 20 hours) platelet counts in the recipients (patients) of PRP-PC, BC-PC and Apheresis-PC

Table 4 Platelet counts and increments in patients of the three study groups

Time of sampling		Platelet counts		
		Patients transfused PRP-PC (n=20)	Patients transfused BC-PC (n=20)	Patients transfused Apheresis-PC (n=20)
Pre-transfusion		9.7±10 × 10^3/µl (1–35 × 10^3/µl)	7.4±7.1 × 10^3/µl (2–30 × 10^3/µl)	10.6±14 × 10^3/µl (2–68 × 10^3/µl)
Post-transfusion (1 hour)	Count	35.9±15 × 10^3/µl (15–70 × 10^3/µl)	31.9±14 × 10^3/µl (13–71 × 10^3/µl)	*53.4±27.6 (11–109 × 10^3/µl)
	Increment	26.1±8.7 × 10^3/µl (12–47 × 10^3/µl)	25±11.9 × 10^3/µl (9–60 × 10^3/µl)	*43.1±24.2 × 10^3/µl (9–95 × 10^3/µl)
Post-transfusion (20 hours)	Count	31.3±13.7 × 10^3/l (13–64 × 10^3/µl)	26.1±13.5 × 10^3/µl (11–65 × 10^3/µl)	*46.2±25.1 × 10^3/µl (8–90 × 10^3/µl)
	Increment	21.5±8.7 × 10^3/µl (10–43 × 10^3/µl)	20.7±11.6 × 10^3/µl (7–57 × 10^3/µl)	*35.6±22.3 × 10^3/µl (6–77 × 10^3/µl)
CCI	1 hour	16.5±4.2 × 10^3/µl (12.5–30.6 × 10^3/µl)	16.4±1.9 × 10^3/µl (13.4–20.1 × 10^3/µl)	16.9±6.3 × 10^3/µl (12–39 × 10^3/µl)
	20 hours	13.3±3.8 × 10^3/µl (8.5–27.2 × 10^3/l)	13.4±1.9 × 10^3/µl (9–17.5 × 10^3/µl)	13.8±6.1 × 10^3/µl (8.6–33.8 × 10^3/µl)
PR	1 hour	37.7±10.7 × 10^3/µl (30.6–72.2 × 10^3/µl)	36.7±5.5 × 10^3/µl (30.2–48.4 × 10^3/µl)	41.1±11.1 × 10^3/µl (30.1–97.4 × 10^3/µl)
	20 hours	30.7±10.0 × 10^3/µl (27–66.8 × 10^3/µl)	30.1±5.4 × 10^3/µl (21.1–41.8 × 10^3/µl)	33.5±15.2 × 10^3/µl (20.2–83.9 × 10^3/µl)

Counts: Mean ± SD (range)

*Statistically significant (p value < 0.01 to 0.007)

benefit from prophylactic administration of platelets. This is particularly true of a patient with a temporary thrombocytopenia consequent to myelosuppressive therapy: It is common practice to pre-select level of thrombocytopenia to decide when to transfuse platelets prophylactically" [8]. The threshold platelet count at which platelets are prophylactically transfused remains controversial but most clinicians choose between 10,000/µl to 20,000/µl.

In this study out of 60 patients, 41 (68.3%) required therapeutic platelet transfusion support, while 19 (31.7%) needed prophylactic transfusion. Majority of patients received platelet transfusion when they had pre-transfusion platelet count < 20,000/µl.

The dose of platelets as determined by the number of platelets in single donor platelets or in random donor platelets has not been standardized. A single donor platelet concentrate containing approximately 3 × 10^{11} platelets is expected to raise platelet count by 30,000 – 60,000/µl, while random donor platelets containing approximately 7 × 10^{10} platelets increases the platelet count by 5,000–10,000/µl in an average sized adult. Most institutions adopted policies for "standard" platelet dose to give one platelet concentrate /10 kg of body weight and this should increase the platelet count by approximately 40,000/l.

One recent controversy has been the issue of whether it is more economical and cost effective to give "low" or "high" doses of platelets to patients. It has been argued that it is more effective to only give 3–4 units of platelets as a standard dose than 8-10 units [9].

The response to platelet transfusion can be determined accurately by corrected count increment (CCI) and percentage recovery (PR) at one hour and 20 hours post-transfusion. O'Connel et al [10] reported no difference between 10 minutes and 1 hour post-transfusion platelet count and this provides a quick and accurate method of determining platelet recovery. Post-transfusion platelet recovery is usually about 60% of the number of autologous platelets transfused, but may be as low as 20% to 40% after homologous transfusion in patients with factors affecting platelet recovery [11]. The post-transfusion platelet count is affected by the viability of the platelets as well as the number of platelets in the platelet concentrates. It is also affected by the dilution of platelets in the patient's blood volume. CCI and PR are measures that have been used to correct the post-transfusion platelet count for the patient's blood volume and for the number of platelets in the platelet concentrates.

In the present study post-transfusion increments, CCI and PR were analyzed both with respect to the platelet preparation and the underlying disease condition of the patients. In patients with aplastic anemia who received Apheresis-PC, the post-transfusion platelet counts and increments achieved were significantly higher as compared to patients

who received PRP-PC and BC-PC. However when CCI and PR were calculated, the results with all the three preparations were comparable.

In a study reported by Norol et al [12] comparing the platelet doses, increments and PR in AML patients who had undergone allogenic BMT, it was observed that higher the dosage, higher was the platelet counts, increments but percentage recovery was similar. Three platelet doses [(medium dose ($2–4 \times 10^{11}$ platelets), high dose ($4–6 \times 10^{11}$ platelets) and very high dose ($>6 \times 10^{11}$ platelets)] were transfused. The author showed that increments in 12 hours post-transfusion platelet count and the time to next transfusion increased with higher platelet doses and this difference was statistically significant ($p<0.01$ to 0.05), but the percentage recovery was similar in all three groups and statistically not significant. The results of Norol's study was also comparable to our study and we found that those patients who received lower doses (i.e. PRP-PC and BC-PC recipients) had significantly low post-transfusion platelet counts and increments at 1 hour and 20 hours as compared to patients who received medium dose (Apheresis-PC). There was significantly increase in inter-transfusion interval with Apheresis-PC than with PRP-PC and BC-PC recipients [(Mean±S.D.), 4.7±1.33 days Vs 2.7±0.82 days Vs 2.5±0.7 days respectively] ($p<0.05$). The post transfusion therapeutic efficacy assessed by CCI and PR at 1 hour and 20 hours were comparable in all three groups of patients.

Klumpp et al [13] used a similar methodology to compare low dose (mean = 3.1×10^{11} platelets) vs. high dose (mean = 5.0×10^{11} platelets). On comparison with high dose platelets, low dose platelets resulted in a lower platelet count increment and shorter transfusion free survival. In fact in studies depicting mathematical model of platelet kinetics show that, platelet loss is caused by senescence and due to random processes, presumed to be primarily the maintenance of vascular hemostasis. This random removal of platelets represents < 20% of platelet turnover in patients with normal platelet counts and this random loss increases to 100% in severely thrombocytopenic patients. Based on these data, the number of platelets required by an average person to maintain hemostasis is estimated to be 3.6×10^{10} platelets/L/day. Even with one third of platelets being sequestered in a normal-size spleen, transfusing one unit of RDP (minimum of 5.5×10^{10} platelets) would provide sufficient platelets necessary to maintain hemostasis. Based on this model transfusing large doses of platelets would lead to higher percentage of platelets being lost due to senescence and thereby increase total platelet utilization [14, 15].

Although quality assessment and transfusion of platelets was done within 24 hours of transfusion in this study the results of quality testing of PRP-PC and BC-PC in our department comply within recommended standards up to day 3 of storage – which is presently the maximum storage period of platelets in our department. Apheresis-PCs are prepared on demand and hence issued soon after preparation.

Hence, there does not appear to be any significant difference in the efficacy of platelet transfusion whether the concentrates are prepared from Platelet Rich Plasma or Buffy Coats or are collected by Apheresis. The decision to use any of these products is largely based on cost and availability which are two important factors in a developing country.

Conclusions

Thus from the present study it can be concluded that the platelets prepared by all the three methods are highly satisfactory after preparation. Post-transfusion increments were obtained as expected in severely thrombocytopenic patients with hemato-oncological disorders who did not have any confounding factors. Although post-transfusion increments were significantly higher in patients who received higher doses (Apheresis-PC) as compared to lower dose (PRP-PC and BC-PC) ($p<0.001$), but the CCI and PR were comparable in all three groups of patients, which take into account the patients blood volume, increment and the total platelets transfused.

On the basis of mathematical model of platelet kinetics,transfusing large doses of platelets lead to higher percentage of platelet being lost due to senescence and thereby increase total platelet utilization. So transfusing one unit of random donor platelets (RDP) [minimum of 5.5×10^{10} platelets] would provide sufficient platelets necessary to maintain haemostasis in an average person.

Thus, in developing countries Apheresis platelets, because of their high cost and more technical expertise required may be recommended only in selected patients either when PRP-PC and BC-PC in adequate doses are not available in the inventory, or when HLA-matched platelet transfusions are indicated.

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