

Selected Parameters for Quality Assessment of Platelet Products Available for Transfusion Purpose at Oncology Centers in Basra, Iraq

Rasha Ahmed Talib¹, Sadiq Khalaf Ali²

1. MBChB, Basra health directorate, ministry of health.
2. F.I.B.M.S. Hematopathology, Consultant Hematopathologist, Department of Pathology, Al-Zahraa College of Medicine, University of Basrah

Received: 26.02.2024

Accepted: 24.03.2024

Abstract

Background: Platelet transfusion is significantly involved in the treatment of oncology patients since the disease process as well as many therapeutic agents can induce significant thrombocytopenia. Many variables regarding platelet products were studied over the years to determine the quality of platelet products. The study aimed to assess the quality of platelet-rich plasma platelet concentrate, and apheresis platelet concentrate that are available for transfusion in oncology centres.

Subjects and Methods: A cross-sectional study was conducted at the main blood bank in Basra, Iraq, the blood bank branch in Basra Specialized Children's Hospital, and oncology centres in Basra between May 2023 and September 2023. One hundred fifty apheresis platelet concentrate units and 150 Platelet-rich plasma platelet concentrate units were assessed for their in vitro quality by assessing the volume of platelet concentrate units, platelet count per unit, and residual white blood cell per unit. Fifty patients were assessed for their response to platelet transfusion; half received PRP-PC, and the other half received apheresis platelet concentrate.

Results: Apheresis-PC units met volume and residual WBC criteria (98.08%, 90.38%) better than PRP-PC (61.33%, 5.60%). Final scoring showed 4.6% PRP and 15.3% apheresis-PC, scoring 3. Patient response analysis revealed increased platelet count after transfusion, with a higher number of transfused units for PRP-PC (13 ± 5.28 units) vs. apheresis-PC (1 ± 0.28 units). Recovery was > 20% for 80% of apheresis-PC and 56% for PRP-PC.

Conclusion: Apheresis-PC outperformed PRP-PC in meeting quality standards. Apheresis-PC had a higher platelet count and lower WBC contamination, which makes it a better choice for platelet transfusion to reduce recipient exposure to multiple donors. Recipient differences in age, weight, blood volume, and type of malignancy didn't affect the transfusion response.

Keywords: Quality Assessment, Platelet Products, Blood Transfusion, Oncology, Basra, Iraq

Corresponding author: Dr. Rasha Ahmed Talib, Basra health directorate, ministry of health.

✉ E-mail: rashaahmed1.ib@gmail.com

Introduction

Platelets are non-nucleated, discoid cells, roughly 2–3 μm in diameter which function primarily as regulators of hemostasis but also play secondary roles in the formation of new blood vessels and innate immunity. (1) Defects in platelet production or function are life-threatening due to the risk of bleeding and may demand platelet transfusion. In humans, the reference range for a normal platelet count is $150\text{--}400 \times 10^9/\text{l}$ blood. (2) With a platelet lifetime of approximately eight to ten days, a

production of 10^{11} platelets per day is needed to maintain a constant level. (2) The hemostatic benefits of fresh whole blood were recognized at the beginning of the 20th century (3), later around the mid-century it was concluded that these benefits are probably due to the platelet component of the fresh whole blood (4). Since then, major developments have been introduced to the process of platelet production. This started with the introduction of centrifugation to separate blood products, going through the replacement of glass containers with plastic containers that became gas-permeable with time. The introduction of platelet additive solutions, apheresis, and recently exploring alternative storage methods may help achieve more convenient storage for longer durations of time. (5-7)

The volume of platelet products indicates the amount of added plasma to the platelets. The ratio of platelet count to plasma volume has a direct effect on the maintenance of the critical product pH needed for platelet viability throughout the storage duration, with an accepted ratio of $(1-1.5 \times 10^9 \text{ platelets/mL})$. (8)

Residual WBC in platelet products represent a source of adverse transfusion reactions including (e.g., febrile non-hemolytic transfusion reaction, transmission of infections such as CMV, alloimmunization and platelet refractoriness, and transfusion-associated graft versus host disease). Studies have found that adoption of pre-storage leukocyte reduction reduced the rate of some of these complications especially FNHTR, CMV transmission and development of immune-mediated platelet refractoriness. (9-11)

An adequate platelet count per unit is important to achieve the desired response, especially regarding the interval between transfusions. It was found that transfusion of lower platelet count may achieve a similar hemostatic effect compared to the standard dose, but it will require more frequent transfusions to maintain the desired platelet count (12). This can increase recipient exposure to multiple donors which may increase the risk of alloimmunization. Since a bone marrow transplant may be required in oncology patients, the development of alloimmunization is not desirable.

The study aims to assess the in-vitro quality of Platelet-rich-plasma platelet concentrate, and apheresis platelet concentrate that is used for transfusion purposes in oncology centres, in Basra, Iraq, using selected quality parameters (i.e., the volume of the unit, platelet count per unit, and residual white blood cell count per unit) for this purpose. It also aims to evaluate patients' platelet count response to platelet transfusion. As well as, assessment of any possible associations between the type of platelet product or patients' characteristics and that response.

Patients and methods

This is a five-month cross-sectional study conducted at the main blood bank in Basra, Iraq, the blood bank

branch in Basra specialized children's hospital, and oncology centers in Basra between May 2023 and September 2023. A total of 150 apheresis platelet concentrate units and 150 Platelet-rich plasma platelet concentrate units were assessed for their in vitro quality by assessing the volume of platelet concentrate units, platelet count per unit, and residual white blood cell per unit. A total of 50 patients were assessed for their response to platelet transfusion, half received PRP-PC, and the other half received apheresis platelet concentrate, as shown in Figure 1.

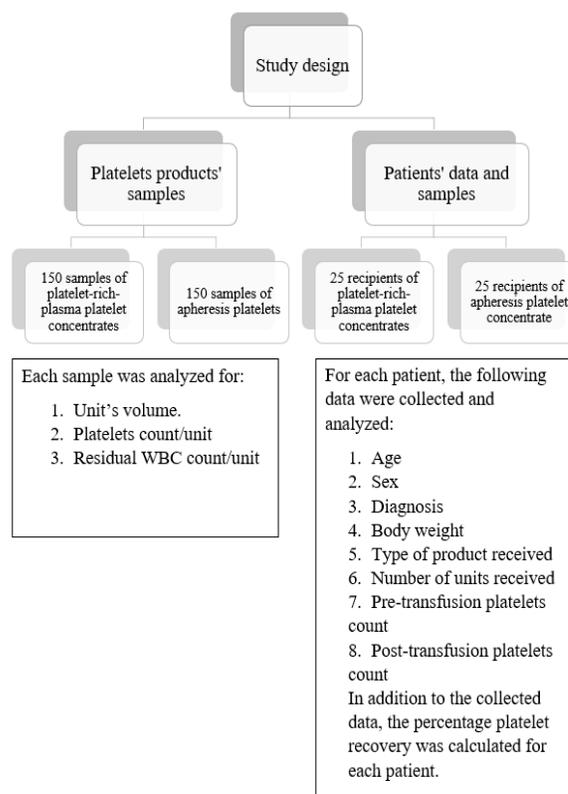


Figure (1): A flow chart of the study design

Two types of platelet products were studied, which are whole blood-derived platelets produced by the platelet-rich plasma method, and apheresis platelets.

Platelet-rich-plasma platelets concentrate (PRP-PC) is produced from whole blood collected in a demotek® quadruple blood bag 450mL (Demophorius® healthcare, Limassol, Cyprus) which uses CPDA-1 as an anticoagulant, which was stored at room temperature ($22^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hours. It is centrifuged by Hettich® Roto Silenta 630 RS centrifuge (Hettich®, Tuttlingen, Germany), the first spin to separate packed red blood cells from platelet-rich plasma, the platelet-rich plasma is expressed into the attached second bag by manual plasma extractor (Lmb® technologies GmbH, Schwaig, Germany), and a second spin to separate platelets as a precipitate from plasma, most of the plasma will be expressed into another attached bag by the manual plasma extractor leaving a small volume for platelet suspension.

The platelet bag is then sealed and separated from the plasma bag using a radiofrequency tube sealer, the product is stored in an incubator that contains horizontal flatbed platelet agitators (Helmer Scientific, Noblesville, Indiana, USA) with 60 rpm frequency, at a temperature of $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$ which is monitored and recorded 3 times daily.

While apheresis platelets, that were collected at Al Basra Specialized Hospital for Children, were produced using Trima Accel® (Terumo BCT, Colorado, USA), and the donations were collected from adult donors in the form of double adult units and a red blood cell unit.

The sampling of (PRP-PC) was done on the same day of production, by expressing the tubing content back into the bag, mixing the bag content to ensure proper sampling, and re-expressing part of the product into the tubing, a segment that contains about 1-2 ml was then sealed, separated, and labelled. The segment is later dispensed into a plain glass tube for analysis within 2 hours of sample collection.

Likewise, sampling of apheresis platelets was done on the same day of collection, by mixing bag content and then expressing 1-2 ml of the product into the small sampling pouch attached to the unit by the manufacturer, the side bag is then sealed and separated from the unit using a radiofrequency sealer,

the sample is dispensed into a plain glass tube for analysis within 2 hours of samples collection.

Both types of platelet products were weighed using an electronic scale with a sensitivity of 0.1 gram (Beurer, Ulm, Germany) to obtain a weight that represents the combined weight of both the product's and the container's weight, the empty bags for both products were also weighed.

Platelet concentrates unit volume was calculated by weighing the unit, subtracting the weight of an empty bag, and dividing the result by the platelet concentrate specific gravity which is 1.03 (13,14) for platelet concentrate suspended in plasma. The volume of platelet concentrate (ml) =
$$\frac{\text{weight of a full PC unit} - \text{weight of empty PC bag}}{\text{specific gravity of PC}}$$

Sysmex® XN-350 blood counter (Sysmex®, Kobe, Hyogo, Japan) was used to determine the platelet count/ μL . Then the platelet count per unit was determined by multiplying the platelet count/ μL by 1000 to determine the count per milliliter and by the unit volume in milliliter.

Platelet count per unit = platelet count/ μL \times 1000 \times volume of PC (ml)

Residual WBC count was estimated for PRP-PC units using the Sysmex®XN-350 blood counter using the whole blood mode.

Since no specialized systems are available for counting the low residual white cell counts in apheresis platelet concentrate units, the Sysmex® XN-350 prediluted mode was used for this purpose. The counts were validated by manually counting residual WBC count using a Neubauer chamber for random 20 samples which matched the automated counts obtained by the prediluted mode of the Sysmex® XN-350.

The residual WBC count obtained as cell/ μL was multiplied by 1000 to convert it into cell/ml and then multiplied by the unit volume in millilitres.

In Apheresis units, the WBC count obtained from the device was divided by 7 to account for the dilution factor proposed by the device and then multiplied by

1000 to convert it into cell/ml and then multiplied by the unit volume in millilitres.

$$\text{Residual WBC count} = \text{WBC count}/\mu\text{L} \times 1000 \times \text{volume of PC (ml)}$$

Platelet units were assessed on the day of preparation (day 0). Any unit that was stored in a temperature out of the range of 20 ± 2 has been excluded.

The obtained parameters were assessed according to the quality control standards for the corresponding component type. Iraqi quality standards were obtained from the quality control unit in Basra Main Blood Bank, as shown in Table 1.

Table 1: Selected parameters of the Iraqi quality standards for platelets products

Product	Volume	WBC count	Platelet count
Random platelet (PRP-PC)	45-70 ml	N/A	$\geq 5.5 \times 10^{10}/\text{unit}$
Apheresis platelets	150-380 ml	$\leq 1 \times 10^6/\text{unit}$	$\geq 2 \times 10^{11}/\text{unit}$

N/A: no quality standard, a minimum of 75% compatible products is considered sufficient.

Regarding patients' response to platelet transfusion, patients' records were reviewed for patients' age, sex, diagnosis, weight, and pretransfusion platelet count within 24 hours before platelet transfusion, and the type and number of transfused platelet units. Patients' blood samples were collected, in EDTA tubes, within 20 hours of platelet transfusion, and platelet count was obtained by automated blood counter (Sysmex® XN-350).

The data of fifty patients were collected, 25 of whom were transfused with whole-blood derived platelets, which were prepared by the platelet-rich plasma methods, the transfused units were not ABO-matched to the patient's blood groups and of different storage durations. The other 25 were transfused with apheresis-derived platelets, the transfused units were mostly ABO-matched to the patient's blood groups and of variable storage durations.

Patients who received platelets transfusion within a period longer or shorter than 20 hours were excluded from this study. Likewise, patients with peripheral causes of thrombocytopenia (immune thrombocytopenic purpura, thrombotic thrombocytopenic purpura, heparin-induced thrombocytopenia, sepsis, disseminated intravascular coagulation, and hypersplenism) were excluded from the study.

Blood volume for patients was calculated using the following equation:

$$\text{Blood volume (ml)} = \text{patient's weight (kg)} \times \text{Average blood volume for age (ml/kg)}$$

Average blood volume for age is shown in Table 2. (15-17)

Table 2: Average blood volume for age (ml/kg)

Age	Average blood volume for age (ml/kg)
Preterm neonate	95
Neonate	85
infant <3 months	85
Child > 3months	75
Adolescent male	70
Adolescent female	65
Adult male	75
Adult female	65

The response to transfusion was assessed by calculation of the percentage platelet recovery (PPR)

$$\text{PPR} = \frac{(\text{C post} - \text{C pre}) \times \text{total blood volume (L)} \times 100\%}{\text{number of platelets transfused (} 10^{11} \text{)}}$$

Where C post: post-transfusion platelet count (platelet/L) C pre: pre-transfusion platelet count (platelet/L)

Adequate post transfusion increment is defined as $\text{PPR} \geq 30\%$ after 1 hour of platelet transfusion, and $\text{PPR} \geq 20\%$ after 20 hours of platelet transfusion. (18)

Two platelet percentage recovery values were calculated for each patient, one that represented the response if the minimum standard platelet count per unit was transfused, which in this study is represented as standard percentage platelet recovery, and the other represented the response to the average platelet count per unit calculated in this study, which is represented as the corrected platelet percentage recovery.

The agreements of the scientific and ethical committees in both the Iraqi Board for Medical Specializations and Basrah Health Directorate were obtained before carrying on this research, and verbal consent from patients or their next of kin was obtained for the collection of data and blood samples. Full adherence to aseptic techniques was ensured while collecting samples from platelet units.

The data were coded and analysed using the Statistical Package for the Social Sciences (SPSS) version 26. The p-value was considered significant if <0.05, very significant if <0.01 and highly significant if <0.001.

Results

The mean volume of the apheresis PC unit was 172.80 ± 10.24 (mean \pm SD). Nearly all the units (98.08%) met the desired quality control criteria of volume (150–380 ml). Regarding the mean platelet count of apheresis-PC units, it was $1.28 \pm 0.55 \times 10^{11}$ (mean \pm SD)/unit. Of them, only 15.38% met the quality control criteria ($\geq 2 \times 10^{11}$ /unit). Concerning the WBC count, the mean WBC count was $0.46 \pm 0.44 \times 10^6$ /unit. The majority of units (90.38%) met the criteria and had less than 1×10^6 /unit WBC contamination, as shown in Table 3.

Table 3: In vitro quality assessment of apheresis platelet concentrate units (n = 150)

Apheresis-PC	Mean	Median	Range	Agreement
Volume/ml	172.80 ± 10.24	174.52	149.71-195.73	98.08%
Platelet count * 10^{11} / unit	1.28 ± 0.55	1.15	0.14 – 2.38	15.38%
WBC count * 10^6 / unit	0.46 ± 0.44	0.25	0 -1.6	90.38%

Table 4 represents the quality assessment of Platelet-rich plasma platelet concentrate units (PRP-PC). The mean volume of units was 65.70 ± 11.82 ml (mean \pm SD). About two-thirds of the units (61.33%) met the desired quality control criteria of volume (45-70 ml). The mean platelet count of PRP-PC units was $2.16 \pm 2.16 \times 10^{10}$ (mean \pm SD)/unit. The majority of units did not meet the criteria and only 8.00% of them met the quality control criteria ($\geq 5.5 \times 10^{10}$ /unit). About the WBC count, the mean WBC contamination count was $5.60 \pm 5.46 \times 10^6$ /unit.

Table 4: In vitro quality assessment of Platelet-rich plasma platelet concentrate units (n = 150)

PRP-PC	Mean	Median	Range	Agreement
Volume/ml	65.70 ± 11.82	65.69	39.52 – 95.44	61.33%
Platelet count * 10^{10} / unit	2.16 ± 2.16	1.57	0.19 – 17.80	8.00%
WBC count * 10^6 / unit	5.60 ± 5.46	4.30	0.42 – 46.00	-

Table (5) represents the final scoring for examined platelets units, a final score was given for each unit based on the number of national quality criteria it satisfied, it's worth mentioning that Iraqi quality standards for PRP-PC units don't specify a residual WBC count; therefore, all PRP-PC units were considered satisfactory for this criterion and were given a point in this regard.

Each unit scored out of 3, 4.66% (7 units) of PRP-PC have scored 3 out of three, more than half of PRP-PC units 58.66% (88 units) scored 2 out of three, and 36.66% (55 units) scored only 1 out of 3. On the other hand, 15.3% (23 units) of apheresis platelets units scored 3 out of 3, the majority of apheresis units 73.3% (110 units) scored 2 out of 3, and 11.3% (17 units) of them scored 1 out of 3. None of the PRP-PC or apheresis-PC scored 0 out of 3

Table 5: Final scoring for the examined platelet units

Score	PRP-PC	Apheresis-PC
3	7 (4.66%)	23 (15.33%)
2	88 (58.66%)	110 (73.33%)
1	55 (36.66%)	17 (11.33%)
0	0 (0%)	0 (0%)
Total	150 (100%)	150 (100%)

In the second part of the study, the data of fifty patients were collected. Twenty-five of them received apheresis-PC, and 25 received PRP-PC. Sixty percent of the apheresis-PC recipients and 52.0% of PRP-PC recipients were females, and most of the patients who received PRP-PC (40.0%) were diagnosed with chronic haematological neoplasms or disorders, while 36.0% of patients who received apheresis-PC were diagnosed with acute myeloid leukemia.

The blood volume was higher among the PRP-PC with a mean equal to 4.13 ± 0.91 than in the apheresis-PC and the results were statistically significant (P-value = 0.001) as shown in table 6.

Table 6: Demographic and clinical characteristics of the study population

Demographic and clinical characteristics		Apheresis-PC (n=25)	PRP-PC (n=25)	P- value
Age	Mean \pm SD (Age group range)	13.63 \pm 18.48 (13.23 – 36.08)	38.28 \pm 21.55 (13.4 – 36.07)	0.001*
	Sex			
Sex	Male	10 (40.0%)	12 (48.0%)	0.776**
	Female	15 (60.0%)	13 (52.0%)	
Clinical diagnosis	Acute myeloid leukemia	9 (36.0%)	6 (24.0%)	0.422***
	Acute lymphoblastic leukemia	6 (24.0%)	6 (24.0%)	
	Chronic hematological neoplasms/disorders	5 (20.0%)	10 (40.0%)	
	Non hematological neoplasms	5 (20.0%)	3 (12.0%)	
Weight	Mean \pm SD	28.20 \pm 19.19	58.72 \pm 9.94	0.001*
Blood volume (L)	Mean \pm SD	2.02 \pm 1.33	4.13 \pm 0.91	0.001*

* Independent sample t-test
** Chi-square test
*** Fisher exact test

Table 7 shows that the mean platelet counts after receiving both apheresis-PC and PRP-PC were 47.40 ± 26.31 and 42.04 ± 43.80 , respectively, which was significantly higher than before transfusion with a P-

value equal to 0.001, and the change in platelet count was 34.76 ± 26.22 in the apheresis-PC receiver and 24.60 ± 32.27 among the PRP-PC.

Table 7: Platelet count before and after receiving apheresis-PC and PRP-PC transfusion

Platelet concentrates	Mean count before platelet transfusion ($\times 10^9/L$)	Mean count after platelet transfusion ($\times 10^9/L$)	P-value	Mean platelet increment ($\times 10^9/L$)
Apheresis-PC	12.64 \pm 6.08 (25)	47.40 \pm 26.31 (25)	0.001	34.76 \pm 26.22
PRP-PC	17.44 \pm 12.04 (25)	42.04 \pm 43.80 (25)	0.001	24.60 \pm 32.27

* Paired sample t-test

The mean number of units transfused was 13 ± 5.28 in the PRP-PC receiver and 1 ± 0.28 units in the apheresis platelet concentrate receiver, as described in Table (8).

Table 8: Platelet transfusion in study groups

Platelet transfusion	Apheresis-PC	PRP-PC	P-value
Number of units	1 \pm 0.28	13 \pm 5.28	0.001
Total	25	25	

* Independent sample t-test

Table 9 represents the response to transfusion assessed by calculating the percentage platelet recovery (PPR). By calculating the standard percentage platelet recovery, 52.0% of those who received apheresis-PC and only 28.0% of those who received PRP-PC had a percentage recovery of $\geq 20\%$ after twenty hours. The corrected percentage platelet recovery of $\geq 20\%$ after 20 hours of platelet transfusion was seen in 80.0% of those who received apheresis-PC concentrate and 56.0% of those who

received PRP-PC; however, there was no statistically significant association between them (P-value > 0.05).

Table 9: The response to transfusion by assessing the percentage platelet recovery (PPR)

Percentage platelet recovery	Apheresis-PC	PRP-PC	P-value	
Standard percentage platelet recovery	≥20	13 (52.0%)	7 (28.0%)	0.148
	<20	12 (48.0%)	18 (72.0%)	
Corrected percentage platelet recovery	≥20	20 (80.0%)	14 (56.0%)	0.128
	<20	5 (20.0%)	11 (44.0%)	
Total	25 (100.0%)	25 (100.0%)		

* Chi-square test

The association between corrected percentage platelet recovery and certain variables is shown in Table (10). Regarding the type of platelet concentrate, although both apheresis-PC and PRP-PC showed a percentage of platelet recovery of more than 20 percent (80.0% and 56.0%, respectively), the association was not significant. A higher percentage recovery of platelets was seen among all types of neoplasms, and a lower percentage recovery was seen among older age groups (30.59 ± 24.38) and those with a higher weight (49.56 ± 20.95). However, all the variables were not statistically associated with the corrected percentage platelet recovery or a certain variable (P-value > 0.05).

Table (10): The association between corrected percentage platelet recovery and certain variables

Variables		Corrected percentage platelet recovery		P-value
		≥20 (n=34)	<20 (n=16)	
Platelet concentrates	Apheresis-PC	20 (80.0%)	5 (20.0%)	0.066**
	PRP-PC	14 (56.0%)	11 (44.0%)	
Diagnosis	Acute myeloid leukemia	10 (66.6%)	5 (33.3%)	0.975**
	Acute lymphoblastic leukemia	8 (66.7%)	4 (33.3%)	
	Chronic hematologic neoplasms/disorders	11 (73.3%)	4 (26.7%)	
	Non hematologic neoplasms	5 (62.5%)	3 (37.5%)	
Age	Mean ± SD	23.77 ± 21.02	30.59 ± 24.38	0.355*
Weight		40.59 ± 21.59	49.56 ± 20.95	0.172*

*Independent sample t-test
** Fishers exact test

Discussion

Platelet transfusion is significantly involved in the treatment of oncology patients since the disease process as well as many therapeutic agents can induce significant thrombocytopenia. Both the patient's in vivo environments and ex vivo processing and storage of platelets can affect platelets' survival and efficacy post-transfusion. (19,20)

Regarding platelet unit volume, in the current study, PRP-PC mean volume is 65.7 ± 11.82 mL and 61.33% of the units have satisfied the national quality criteria for volume. The units' volume is comparable to those found by Singh et. al. (14), Toora et. al. (21), and Talukdar et. al. (22). The addition of plasma to the platelet units in this method was done manually. The lack of an objective method to determine the volume of added plasma may have led to over/under-estimation of the plasma volume and, hence may explain the findings.

Regarding apheresis platelet units, the mean volume in the current study is 172.8 ± 10.24 mL and 98.08% of units have successfully achieved the desired volume according to Iraqi quality standards. The units' volume is comparable to that found by an Iraqi study by Waleed A (23), as well as those found by Singh et. al. (14). However, it was lower than the mean volumes reported by a study by Al Rahal N in Iraq (24) and Toora et. al.,(21). The percentage of units that satisfied the national quality standards was comparable to the findings of Singh et. al.(14), Toora et. al.(21).

Concerning the platelet count per unit, in our study, PRP-PC average count per unit is $2.16 \pm 2.16 \times 10^{10}$ /unit; the percentage of units that satisfied the standard platelet count of $\geq 5.5 \times 10^{10}$ /unit is only 8%, the average platelet count per unit was comparable to that found by Talukdar et. al., (22) yet it was lower than what was reported by Singh et. al.(14) and Toora et. al. (21), similarly, the percentage of satisfactory units was much lower than that found by Singh et. al. (14) and Toora et. al.(21) which was 78.2% and 84% respectively.

This low percentage of units that satisfy the national standard for platelet count per unit may be related to the lack of standardized storage incubators with controlled temperatures for collected blood before the components separation procedure, the use of almost all collected blood units for platelet production regardless of blood collection duration, which is recommended to be not longer than 20 minutes according to the AABB technical manual. (25), old or faulty equipment used for the separation of the blood components and factors related to staff training and adherence to standard of practice. Addressing these factors may improve the outcome of platelet concentrate production.

Apheresis platelet units in the current study have an average platelet count per unit of $1.28 \pm 0.55 \times 10^{11}$ /unit and only 15.38% of units met the national quality standard of platelet count per unit $\geq 2 \times 10^{11}$ /unit which is similar to the European quality standard (26) but lower than AABB and Indian (DGHS) standards (platelet count $\geq 3 \times 10^{11}$ /unit) (27,28) which were used in some of the comparable

studies. The average count per unit was lower than the average count reported by both Waleed A. (23) and Al Rahal N.(24) in Iraqi studies, but higher than the average count reported by Talukdar et. al. (22). Both the average count and agreement were significantly lower than those seen in studies by Singh et. al.(14), Chaudhary et. al. (29).

Factors that may affect the yield of platelets by apheresis procedure include pre-donation platelet count, the volume of blood processed, and the processing time (30). Other factors may be implicated including leucocyte count, hemoglobin, age, and body weight that were considered in some studies but not well-established. In terms of leucocyte contamination of the products, the national standards did not assign a value for an acceptable level of contamination in PRP-PC; however, the average residual WBC count per unit in our study was $5.6 \pm 5.46 \times 10^6$ /unit, these values were significantly lower when compared to values obtained by Singh et. al. (14) and Talukdar et. al (22).

The level of WBC contamination In apheresis platelet is $0.46 \pm 0.44 \times 10^6$ /unit, and the percentage of satisfactory units is 90.38%, these findings are lower in terms of average count than those of Singh et. al. (14) and Talukdar et. al.(22), with a better agreement when compared to Al Rahal N (24) study. It's worth mentioning that national Iraqi criteria have lower values for acceptable WBC contamination ($< 1 \times 10^6$ /unit), while the DGHS Indian criteria followed by comparable studies accepts WBC contamination of up to 5×10^6 /unit. (28). Regarding final scoring, the finding is comparable to Toora et. al (21) and Talkudar et. al. (22) while the opposite was found by Singh et. al.(14).

Regarding the demographic characteristics of the recipients, the average age in the apheresis PC recipients group was lower than the average age of the PRP-PC recipients group, that can be explained by the difference in prescription practices among clinicians treating pediatric patients and those treating adult patients, the underlying cause of thrombocytopenia which may or may not be an indication for future bone marrow transplant, and the better availability of

apheresis-PC in the pediatric oncology center in Basra, Iraq.

Concerning the weight of the recipients, the average weight of apheresis-PC recipients (28.20 Kg) was lower than the average weight of the PRP-PC recipients' group (58.72 Kg), which was translated to a significant difference in the calculated total blood volume between the two groups, this difference can be explained by the significant difference in the age groups between the recipients of each product.

In terms of sex, forty percent of apheresis-PC recipients were males while 48% of PRP-PC recipients were males. A higher percentage of male recipients was seen in the study by Slichter et al. (31). Regarding the clinical diagnosis, the diagnosis of AML was the most common among recipients of apheresis-PC, while chronic hematological neoplasms and disorders were the most common category of PRP-PC recipients. This can also be explained by the difference in age between the two groups.

This study has found a highly significant difference (p value <0.001) between the average number of transfused PRP-PC and the average number of transfused apheresis-PC units. This difference can be explained by the higher platelet count per unit of apheresis-PC which means fewer units are needed to reach the desired dose of platelets, in combination with the findings that recipients of apheresis-PC were young individuals with lower weight and total blood volume. There was a highly significant difference (p value < 0.001) between pretransfusion platelet count and post-transfusion platelet count for both groups. This was comparable to the findings by Ning et. al. (32). Higher average increment in platelet count among apheresis PC recipients may be explained by the lower blood volume in this group.

In this study, recipient response in terms of percentage platelet recovery was calculated once for a standard platelet count per unit and another for the average platelet count per unit. A higher percentage of recipients had $>20\%$ corrected percentage platelet recovery after 20 hours of transfusion for both products than those who had $<20\%$ corrected percentage platelet recovery. A higher percentage of

recipients of both products achieved a corrected percentage platelet recovery $> 20\%$ than those who achieved a standard percentage platelet recovery $>20\%$, which is explained by the low average platelet count per unit when compared to the standard platelet count per unit. The corrected percentage platelet recovery had no significant association with the type of product, or recipients' variables in terms of age, body weight, or diagnosis.

Conclusions

The current study demonstrated that apheresis-PC has satisfied more quality standards (volume in 98.08% and residual WBC count in 90.38% of units) than PRP-PC which failed to reach the threshold of 75% satisfactory units for both platelet count per unit and volume, apheresis-PC has also failed to satisfy the 75% threshold for platelet count per unit; however, in comparison between the two products, apheresis-PC has higher average platelet count per millilitre and lower WBC contamination, which makes it a better choice for platelet transfusion to reduce recipient exposure to multiple donors.

The apheresis-PC recipients' group was younger, with lower body weight, lower total blood volume, and a higher prevalence of acute leukemias both myeloid and lymphoid when compared to the PRP-PC recipients' group; however, none of these differences was significantly associated with their response to platelets transfusion.

Reference

1. Thon JN, Italiano JE. Platelets: Production, Morphology and Ultrastructure. In: Gresele P, Born G, Patrono C, Page C, editors. Antiplatelet Agents. Vol. 210, Handbook of Experimental Pharmacology. Berlin, Heidelberg: Springer; 2012.
2. Daly ME. Determinants of platelet count in humans. *Haematologica*. 2011;96(1):10-13.
3. Duke WW. The relation of blood platelets to hemorrhagic disease: description of a method for determining the bleeding time and coagulation time and report of three cases of

- hemorrhagic disease relieved by transfusion. *Journal of the American Medical Association*. 1910;55(14):1185-92.
4. Freireich EJ, Schmidt PJ, Schneiderman MA, Frei III E. A comparative study of the effect of transfusion of fresh and preserved whole blood on bleeding in patients with acute leukemia. *New England Journal of Medicine*. 1959;260(1):6-11.
 5. Fisk JM, Pisciotto PT, Snyder EL, Perrota PL. Platelets and related products. Hillyer CD, Silberstein LE, Ness PM, Anderson KC, Roback JD. *Blood banking and transfusion medicine, basic principle and practice*. 2007.
 6. Janatpour KA, Holland PV. A Brief History of Blood Transfusion. Hillyer CD, Silberstein LE, Ness PM, Anderson KC, Roback JD. *Blood banking and transfusion medicine, basic principle and practice*. 2007.
 7. Rock G, Swenson SD, Adams GA. Platelet storage in a plasma-free medium. *Transfusion*. 1985;25(6):551-6.
 8. van der Meer PF, Bontekoe IJ, Kruit G, Peeters G, van Toledo PJ, Tomson B, de Korte D. Volume-reduced platelet concentrates: optimization of production and storage conditions. *Transfusion*. 2012;52(4):819-27.
 9. Da Ponte A, Bidoli E, Talamini R, Steffan A, Abbruzzese L, Toffola RT, De Marco L. Pre-storage leucocyte depletion and transfusion reaction rates in cancer patients. *Transfusion Medicine*. 2005;15(1):37-43.
 10. Weisberg SP. CMV-Safe Blood Products. In *Transfusion Medicine and Hemostasis 2019* (pp. 271-275). Elsevier.
 11. Seftel MD, Growe GH, Petraszko T, Benny WB, Le A, Lee CY, Spinelli JJ, Sutherland HJ, Tsang P, Hogge DE. Universal prestorage leukoreduction in Canada decreases platelet alloimmunization and refractoriness. *Blood*. 2004;103(1):333-9.
 12. Riley W, Smalley B, Pulkrabek S, Clay ME, McCullough J. Using lean techniques to define the platelet (PLT) transfusion process and cost-effectiveness to evaluate PLT dose transfusion strategies. *Transfusion*. 2012;52(9):1957-67.
 13. Keever-Taylor CA, Schmidt K, Zeng H, Morris D, Heidtke S, Konings S, Margolis DA. Determination of the volume of hpc, apheresis products based on weight in grams. *Blood*. 2014;124(21):3850.
 14. 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 journal of transfusion science*. 2009;3(2):86-94.
 15. Butterworth JF, Mackey DC, Wasnick JD. Fluid Management & Blood Component Therapy. In: Butterworth JF, Mackey DC, Wasnick JD, editors. *Morgan & Mikhail's clinical anesthesiology*. 5th ed. New York: McGraw Hill; 2013. P. 1161-1182.
 16. Hazinski MF. Nursing care of the critically ill child. Philadelphia: Elsevier Health Sciences; 2012.
 17. Howie SR. Blood sample volumes in child health research: review of safe limits. *Bull World Health Organ*. 2011; 89(1):46-53.
 18. Stanworth SJ, Navarrete C, Estcourt L, Marsh J. Platelet refractoriness—practical approaches and ongoing dilemmas in patient management. *British journal of haematology*. 2015;171(3):297-305.
 19. Rinder HM, Smith BR. In vitro evaluation of stored platelets: is there hope for predicting posttransfusion platelet survival and function?. *Transfusion*. 2003;43(1):2-6.
 20. Cohn CS. Platelet transfusion refractoriness: how do I diagnose and manage?. *The American Society of Hematology Education Program Book*. 2020;2020(1):527-32.

21. Toora E, Kulkarni RG, Manivannan P, Sastry AS, Basavarajegowda A, Sahoo D. Quality assessment of platelet concentrates prepared by platelet-rich plasma, buffy-coat, and apheresis methods in a tertiary care hospital in South India: A cross-sectional study. *Asian Journal of Transfusion Science*. 2023;17(2):239-245.
22. Talukdar B, Chakraborty S, Hazra R, Biswas K, Bhattacharya P. Quality assessment of platelet concentrates: A comparative study using three different methods. *Int J Biomed Res*. 2017;8:194-9.
23. Abdelazez W, Ali OA. Evaluation of plateletpheresis procedure in blood component separation unit of Bone Marrow Transplant Center. *IRAQI JOURNAL OF COMMUNITY MEDICINE*. 2007;20.(7):60-62.
24. Al-Rahal K, Nidal. Plateletpheresis concentrate produced with Fresenius cell separator Iraqi experience. *Mustansiriya Medical Journal*. 2012 Jun;11.(1):27-32.
25. Technical Manual, 20th ed. Bethesda: AABB; 2020.
26. European Directorate for the Quality of Medicines & HealthCare. Guide to the preparation, use and quality assurance of blood components. 21st ed. Strasbourg, France: European Directorate for the Quality of Medicines & HealthCare; 2023.
27. Standards for Blood Banks and Transfusion Services, 32nd ed. Bethesda: AABB; 2020.
28. Saran RK, editor. Transfusion medicine: technical manual. Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India; 2003.
29. Chaudhary R, Das SS, Khetan D, Sinha P. Effect of donor variables on yield in single donor plateletpheresis by continuous flow cell separator. *Transfusion and apheresis science*. 2006;34(2):157-61.
30. Geetha C, Pavani M, Korti P, Jayashankar E, Deshpande AK. Factors affecting platelet yield in single donor plateletpheresis: A single institution experience. *Indian Journal of Pathology and Oncology*. 2017;4(1):23-6.
31. Slichter SJ, Davis K, Enright H, Braine H, Gernsheimer T, Kao KJ, Kickler T, Lee E, McFarland J, McCullough J, Rodey G. Factors affecting posttransfusion platelet increments, platelet refractoriness, and platelet transfusion intervals in thrombocytopenic patients. *Blood*. 2005;105(10):4106-14.
32. Ning S, Barty R, Liu Y, Heddle NM, Rochweg B, Arnold DM. Platelet transfusion practices in the ICU: Data from a large transfusion registry. *Chest*. 2016;150(3):516-23.

معايير مختارة لتقييم جودة منتجات الصفائح الدموية المتاحة لأغراض نقل الدم في مراكز الأورام في البصرة، العراق

الخلاصة

المقدمة: يشارك نقل الصفائح الدموية بشكل كبير في علاج مرضى الأورام حيث أن المرض بالإضافة إلى العديد من الطرائق العلاجية يمكن أن تتسبب بنقصان الصفائح الدموية بشكل كبير. أن النقص في إنتاج الصفائح الدموية أو العيوب في وظيفتها مهددة للحياة بسبب خطر النزيف وقد تتطلب نقل الصفائح الدموية. وحيث أن عمر الصفائح الدموية من ثمانية إلى عشرة أيام تقريباً، هناك حاجة إلى إنتاج ١٠^{١١} صفائح دموية يومياً للحفاظ على مستوى ثابت. يمكن أن يؤثر كل من العوامل الداخلية في الجسم الحي ومعالجة الصفائح الدموية وتخزينها في مصارف الدم على بقاء الصفائح الدموية وفعاليتها بعد نقلها للمريض. تمت دراسة العديد من المتغيرات المتعلقة بمنتجات الصفائح الدموية على مر السنين من أجل تحديد جودة منتجات الصفائح الدموية وتقديم بعض المؤشرات التي تؤثر على عمر الصفائح الدموية وفعاليتها بعد نقل الصفائح.

أهداف الدراسة: لتقييم الصفائح العشوائية والصفائح الفصادة المتاحة لنقل الدم في مراكز الأورام، مع الأخذ في نظر الاعتبار الحجم وعدد الصفائح الدموية وعدد خلايا الدم البيضاء، وتقييم استجابة المرضى واستكشاف الارتباطات مع العوامل المختلفة.

منهجية البحث: دراسة مقطعية استمرت خمسة أشهر أجريت في بنك الدم الرئيسي في البصرة، العراق وفرع بنك الدم في مستشفى البصرة التخصصي للأطفال ومراكز الأورام في البصرة بين مايو ٢٠٢٣ وسبتمبر ٢٠٢٣. تم تقييم ١٥٠ وحدة من الصفائح العشوائية و ١٥٠ وحدة من الصفائح الفصادة لنوعيتها في المختبر من خلال تقييم حجم وحدات الصفائح الدموية وعدد الصفائح الدموية لكل وحدة وخلايا الدم البيضاء المتبقية لكل وحدة. ثم تم تقييم ٥٠ مريضاً لاستجابتهم لنقل الصفائح الدموية؛ تلقى نصفهم صفائح فصادة، وتلقى النصف الآخر صفائح عشوائية.

النتائج: قيمت الدراسة وحدات الصفائح الفصادة والصفائح العشوائية في البصرة. استوفت وحدات الصفائح الفصادة الحجم ومعايير كريات الدم البيضاء بشكل أفضل (٩٨,٠٨٪، ٩٠,٣٨٪) من الصفائح العشوائية (٦١,٣٣٪، ٥٠,٦٠٪). كما كشف تحليل استجابة المريض عن زيادة عدد الصفائح الدموية بعد نقل الدم، مع ارتفاع عدد وحدات الصفائح العشوائية المنقولة (١٣ ± ٥,٢٨ وحدة) مقابل الصفائح الفصادة (١ ± ٠,٢٨ وحدة). كانت نسبة استعادة الصفائح الدموية < ٢٠٪ لـ ٨٠٪ من الصفائح الفصادة و ٥٦٪ للصفائح العشوائية. لم يتم العثور على ارتباطات ذات دلالة احصائية بين استعادة الصفائح الدموية ونوع الصفائح الدموية أو التشخيص أو العمر أو الوزن.

الاستنتاجات: تفوقت الصفائح الفصادة على الصفائح العشوائية في تطبيق معايير الجودة. كان لدى الصفائح الفصادة عدد صفائح أعلى، وتلوث أقل بالكريات الدم البيضاء، مما يجعله خياراً أفضل لنقل الصفائح الدموية لتقليل تعرض المتلقي للعديد من المتبرعين. لم تؤثر اختلافات المتلقي في العمر والوزن وحجم الدم ونوع الأورام الخبيثة على استجابة نقل الصفائح.

الكلمات المفتاحية: تقييم الجودة، منتجات الصفائح الدموية، نقل الدم، الأورام، البصرة، العراق.