

Evaluation of the quality of platelet concentrates obtained in a Peruvian hospital

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ABSTRACT

INTRODUCTION Platelet concentrates are blood products obtained from donor's blood, and their conservation must be subject to a strict quality control process to guarantee a safe and high-performance product in treating diseases that require their use.

METHODS We designed a cross-sectional study to determine the total compliance rate in platelet concentrates obtained in the blood bank of the Cayetano Heredia Hospital in Lima during November and December of 2019. The Buffy method Coat obtained the platelet concentrates, and parameters such as platelet count and residual leukocytes, pH, and swirling effect were evaluated according to the National Hemotherapy and Blood Bank Program criteria.

RESULTS The platelet count had a mean of $6.66 \pm 3.94 \times 10^{10}/\mu\text{L}$, the platelet concentrates had a mean of 56.30 ± 6.22 mL, and all, without exception, had the presence of the Swirling phenomenon. The pH had a mean of 7.64 ± 0.15 , while the leukocyte count had a mean of $4.22 \pm 3.51 \times 10^7/\mu\text{L}$. Regarding compliance by the parameters evaluated, it was evident that the platelet and leukocyte count had moderate compliance rates of 43.6% and 24.1%, while the pH and swirling effect had rates of 100% in both cases. The total compliance rate was 54.9% (95% confidence interval: 46.0 to 63.5).

CONCLUSIONS The compliance rate of platelet concentrates is moderate, and it is necessary to implement a process of continuous quality improvement in the blood bank.

KEYWORDS Blood Platelets, Quality control, Blood Bank

INTRODUCTION

The use of platelets is relevant in treating coagulation disorders and managing bleeding caused by thrombocytopenia [1]. Obtaining platelet concentrates (PC) in blood banks (BB) uses various methods, the best known being those based on sedimentation-centrifugation or apheresis [2]. The first is most used in health establishments as the latter needs specific infrastructure and high technology. Sedimentation-centrifugation process is longer, more laborious, and involves greater participation in human manual activity than apheresis [3]. This situation can generate CP unsuitable for heme therapeutic procedures due to non-compliance with quality indicators established by the BB [4]. Transfusion and BB services must ensure optimal use of blood components and ensure that the final product causes minimal or no risk to the

potential recipient. Internal quality control is crucial for a quality management system at the BB and involves having blood products available in a timely manner [5].

In Peru, there are few studies that address quality control of BBs. A decrease in the supply of blood products has been observed in high-complexity hospitals [6]. In relation to the quality of PC, plateletpheresis has been demonstrated as the most effective procedure to obtain platelets [7]. However, it is not known about the quality of PC obtained by manual processes. The BB of Peru is aligned with policies established by the National Program of Hemotherapy and Blood Banks, which defines the objectives that must be achieved in these institutions [8]. One of the strategic objectives of National Program of Hemotherapy and Blood Banks is to improve the quality of supplies generated in hemotherapy centers and BBs. However, as long as compliance with the quality indicators defined within a quality management system is not evident, nonconformities will affect the service and users [9].

The recommended shelf life of PC in storage bags is approximately five days at $22 \pm 2^\circ\text{C}$ with continuous agitation. Platelets undergo several processes with changes starting from collection, processing, storage, and underlying conditions in patients, which can affect the therapeutic benefit to the recipient [10]. Changes in platelet metabolic activity play a

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MAIN MESSAGES

- Platelet concentrates are used in the treatment of bleeding, thrombocytopenia, coagulation disorders and other health problems.
- Quality control of platelet concentrates is critical to guarantee the safety and effectiveness of the product to be transfused.
- Not all blood banks in Peru evaluate compliance with quality indicators of platelet concentrates.
- The evaluation of the quality of blood components allows for the implementation of continuous improvement strategies in blood banks.

crucial role in PC quality, mainly due to changes in pH [11]. However, these are not the only parameters that should be considered to evaluate the quality of PC. Evaluating the quality of PC is a vital, using specific parameters such as the presence of the swirling effect, volume, count of platelets and leukocytes per bag, and pH changes [12].

Our objective was to determine the total compliance rate in PC obtained in the Blood Bank of the Cayetano Heredia Hospital in November and December of 2019. We consider that our study provides relevant information for continuous quality improvement processes in blood banks, specifically in PC management.

METHODS

Study design and population

We designed a cross-sectional study to evaluate PC quality indicators from voluntary blood donors. The PC was obtained at the Blood Bank of the Cayetano Heredia Hospital in Lima between November and December 2019. This hospital is the largest in the northern area of Lima, the capital of Peru. The hospital has a hemotherapy center and blood bank classified as type II by the Peruvian Ministry of Health. According to the care records at the blood bank produces 25 to 30 PC per day, with an average monthly production of 900 concentrates. We included PC obtained by the buffy coat procedure established in the blood bank of the Cayetano Heredia Hospital (see supplementary material 1) and from donors not reactive to the seven serological markers in the blood bank. We excluded PC obtained by apheresis or another procedure.

The number of PC to be evaluated was estimated with a simple proportion calculation in a finite population, assuming a confidence and precision level of 95% and 5% respectively and an expected proportion of nonconformity for platelet concentrates of 10%. Likewise, we considered an ineligible rate of 10%, obtaining a quantity of 133 PC.

Techniques and instruments

Platelet concentrates (PC)

We obtained the platelet concentrates by the Buffy Coat method and according to the procedure approved by the Blood Bank of the Cayetano Heredia Hospital (See supplementary material 1). The platelet concentrates were in bags with a continuous shaking process for five days, where the behavior of the quality indicators was recorded daily. It should be noted

that the quality indicators were measured in each PC on the fifth day of storage, under controlled environmental conditions (Temperature: 20-25°C, and Relative humidity: <70%).

Platelet concentrate quality indicators

Platelet and leukocyte counting: We use a Neubauer chamber (Marienfeld, Germany) for platelet counting and a hematological autoanalyzer (Abbott Diagnostics, model Cell Dynn Emerald, United States) for leukocyte counting based on an electrical impedance principle.

Evaluation of the Swirling Effect: We perform a pairwise visual inspection, observing the presence or absence of the swirl after gently inverting or turning the platelet concentrate up and down. The reading was carried out in front of an LED lamp. The procedure was executed according to Bertolini and Murphy [13].

pH: We use a pH meter (Hanna instruments, United States) after a calibration process with a neutral buffer solution at pH of 7.1. The measurement was performed on a sterile needle aspirate of the PC at a volume of 100 uL, where the pH meter sensor was inserted.

The quality control parameters of the platelet concentrates are observed in supplementary material 2 and were evaluated according to Table 1.

Statistical analysis

The quality parameters in the platelet concentrates were evaluated with descriptive statistics. The total compliance rate of platelet concentrates was estimated by the absolute and relative frequency obtained through compliance with its five quality indicators. We also include the calculation of the 95% confidence interval. We used Stata software (StataCorp College Station, TX, USA) version 17.

Ethics

The study was approved by the Alas Peruanas University Ethics Committee with RD No. 140-19-EPTM-FCS-UAP on August 12, 2019, and administrative permission was obtained from the Cayetano Heredia National Hospital. The information was handled with strict confidentiality, and the blood donors' data was unknown.

Table 1. Quality control parameters of the platelet concentrates.

Parameter	Control frequency	Required quality
Platelet count	Monthly	$> 5.5 \times 10^{10}$ in 75% of the units evaluated
"Swirling" Effect	All the units	Present
Volume	All the units	40 to 70 mL (PRP) and 70 to 90 mL (Buffy coat)
White blood cell count	Monthly	5.5×10^7 to 5.0×10^8
pH	Monthly	> 6.0 at the end of the maximum storage day in 100% of the units evaluated

PRP: platelet rich plasma.

We consider acceptable compliance for each parameter whenever a compliance rate greater than 75% is obtained.

Source: Prepared by the authors of this study.

RESULTS

We evaluated 133 randomly selected platelet units during November and December 2019. The platelet count had an average of $6.66 \pm 3.94 \times 10^{10}/\mu\text{L}$, and the platelet concentrates had an average of 56.30 ± 6.22 mL. All PCs had the presence of the Swirling phenomenon. The pH had a mean of 7.64 ± 0.15 , while the leukocyte counts of $4.22 \pm 3.51 \times 10^7/\mu\text{L}$ (Table 2).

We found that four of the five parameters evaluated were met according to the defined criteria. The platelet count was the only parameter that did not meet the quality standards, with 56.4% of PCs needing compliance. The Swirling effect and pH had absolute compliance in their indicators (Table 3).

Finally, the global analysis showed that only 54.9% (95% CI: 46.0 to 63.5) of the units complied with the National Program of Hemotherapy and Blood Banks standards.

DISCUSSION

The compliance rate of PC is essential data within the quality control of blood products obtained in the BBs. In our case, the results show that approximately 55% of the platelet concentrates meet all the parameters according to PRONA-HEBAS. However, it is essential to emphasize that failure to comply with these parameters is not an indicator for discarding units. However, they are considered to improve the process of obtaining and preserving platelets [14]. Within the five parameters that we used to define "compliant platelet concentrate", some had 100% compliance, independently of the rest of the parameters. Likewise, some units presented average platelet counts above what was evidenced in other studies. We reported an average platelet count of $6.66 \pm 3.94 \times 10^{10}$, while Raturi et al. found an average of 5.89 ± 1.28 (3.1 to 8.7) $\times 10^{10}$ [15]. On the other hand, regarding the residual leukocyte count, our results show higher counts ($4.22 \pm 3.51 \times 10^7$) compared to the referenced study, whose average was $1.5 \pm 1.2 \times 10^7$. The swirling effect was present in all the units similar to our study [15].

It is essential to mention that, in our study, the method for obtaining PC was by Buffy coat, which generates platelet counts very different from other methods, such as obtaining platelet-rich plasma or apheresis. Singh et al. evaluated PC of platelet-rich plasma, buffy coat, and apheresis, showing that the mean platelet count was $7.6 \pm 2.97 \times 10^{10}/\text{unit}$, $7.3 \pm 2.98 \times$

$10^{10}/\text{unit}$, and $4.13 \pm 1.32 \times 10^{11}/\text{unit}$, respectively [16]. In that sense, our findings are similar to those obtained in other studies.

Different studies have shown compliance rates above 95% regarding compliance with quality standards, as evidenced by Bouslama et al. in 475 PC obtained by sedimentation and apheresis. However, the platelet count showed compliance in 58% of their concentrates [17], a figure close to that estimated in our study (55% compliance). These results are even more aligned to what was found by Álvarez and Cueva in a study on 384 PC, whose platelet count compliance was 50.8%. Regarding compliance with parameters such as pH, volume, and swirling effect, they obtained rates of 90.1%, 99.5%, and 97.1%, respectively [18]; while we obtained rates of 100.0%, 97.7%, and 100.0%, evidencing much higher percentages.

Within the study's limitations, given the high demand for PC, evaluations could not be carried out on consecutive days, which would have been ideal to assess the changes in each parameter over time. Nor could probabilistic comparisons be established, considering that only one method was used to obtain platelets. Likewise, carrying out microbiological culture as a quality parameter to verify the products' safety was not possible. However, no adverse event was reported after each platelet concentrate was administered, which is consistent with previous studies [19,20].

It is essential to inform that during the COVID-19 pandemic, the Peruvian Government issued various decrees that progressively resumed economic activities. Care activities through health facilities were not suspended, and blood banks provided continuous care. However, voluntary blood donation campaigns decreased significantly, but replacement donations did not. The last regulation in blood banking was DS 017-2022-MINSA, which modifies the Regulation of Law No. 26454, which declares obtaining, donating, conserving, transfusion and blood supply to be of public order and national interest. However, this standard only requires changes in the organization of blood banks according to the levels of care in health facilities. In the case of our study, the blood bank is located in a level III hospital, whose characteristics did not change with the prerogatives of the standard above.

Finally, this study constitutes essential evidence in the quality control process of the blood bank of the Cayetano Heredia Hospital in Lima, and its results should serve to implement

Table 2. General characteristics of the quality parameters of platelet concentrates.

Parameter	Mean	Standard deviation	Minimum	Maximum
Platelet count (x 10 ¹⁰ /μL)	6.66	3.94	1.24	28.1
pH	7.64	0.15	7.15	7.94
Leukocyte count (x 10 ⁷ /μL)	4.22	3.51	1.03	16.6
Volume (mL)	56.30	6.22	37.86	71.84

Source: Prepared by the authors of this study.

Table 3. Rate of compliant of platelet concentrates according to platelet count.

Indicator	N (%)	95% confidence interval	Compliance (75% or more)
Platelet count			
> 5.5 x 10 ¹⁰ / μL	58 (43.6)	35.4 to 52.2	No
≤ 5.5 x 10 ¹⁰ / μL	75 (56.4)	47.8 to 64.6	
Swirling effect			
Present	133 (100.0)	NA	Yes
Absent	0 (0.0)	NA	
pH			
> 6.2	133 (100.0)	NA	Yes
≤ 6.2	0 (0.0)	NA	
Leukocyte count			
From 5.5 to 50.0 x 10 ⁷ /μL	32 (24.1)	17.5 to 32.1	Yes
< 5.5 x 10 ⁷ /μL	101 (75.9)	67.9 to 82.5	
> 50.0 x 10 ⁷ /μL	0 (0.0)	0.0	
PC volume			
40 to 70 mL	130 (97.7)	93.2 to 99.3	Yes
Less than 40 mL	1 (0.8)	0.1 to 5.2	
Greater than 70 mL	2 (1.6)	0.3 to 5.9	

Source: Prepared by the authors of this study.

corrective and preventive actions as part of the continuous improvement of the service.

CONCLUSIONS

The total compliance rate in PC is moderate and requires improvement actions in the leukoreduction procedure and platelet count. The quality management areas must identify the causes of the parameters whose compliance rate was low, and for this, we recommend using Six Sigma [21] or the Ishikawa method [22]. Finally, it is crucial to guarantee the maintenance and calibration of equipment involved in obtaining CP, especially considering quality standards such as ISO 9001 or 15189 [23,24]. It is important to implement training and updating programs in good manufacturing and quality control practices for BB personnel.

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Evaluación de la calidad de concentrados de plaquetas obtenidos en un hospital peruano

RESUMEN

INTRODUCCIÓN Los concentrados plaquetarios son hemoderivados obtenidos de la sangre, y su conservación debe estar supeditada a un estricto proceso de control de calidad para garantizar un producto inocuo y de alto rendimiento en el tratamiento de enfermedades que requieran su uso.

MÉTODOS Diseñamos un estudio transversal que tuvo por objetivo determinar la tasa de conformidad total en concentrados plaquetarios obtenidos en el banco de sangre del Hospital Cayetano Heredia de Lima durante los meses de noviembre y diciembre del año 2019. Los concentrados plaquetarios fueron obtenidos por el método de Buffy Coat y se evaluaron parámetros como el recuento de plaquetas y leucocitos residuales, pH y efecto swirling, según criterios del Programa Nacional de Hemoterapia y Bancos de Sangre.

RESULTADOS El recuento de plaquetas tuvo una media de $6.66 \pm 3.94 \times 10^{10}/\mu\text{L}$ y los concentrados plaquetarios tuvieron una media de $56.30 \pm 6.22 \text{ mL}$, y todos sin excepción tuvieron presencia de fenómeno Swirling. El pH tuvo una media de 7.64 ± 0.15 , mientras que el recuento de leucocitos tuvo una media de $4.22 \pm 3.51 \times 10^7/\mu\text{L}$. En cuanto al cumplimiento por parámetro evaluado, se evidenció que el recuento de plaquetas y leucocitos tuvieron tasas de conformidad de 43.6% y 24.1%, mientras que el pH y efecto swirling tuvieron tasas del 100% en ambos casos. La tasa de conformidad total fue 54.9% (CI95%: 46.0 a 63.5).

CONCLUSIONES La tasa de conformidad de los concentrados plaquetarios es moderada, y se requiere implementar un proceso de mejora continua de la calidad en el banco de sangre.



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