

Probability of a successful platelet dose according to the number of platelet concentrates

Probabilidad de una dosis de plaquetas exitosa según el número de concentrados plaquetarios

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Abstract

Introduction: Platelet transfusion for prophylactic or therapeutic purposes is a common practice. The outcome evaluated in using platelets for prophylactic purposes has been preventing clinically significant bleeding. Transfusion guidelines recommend using platelet transfusion for prophylactic purposes based on the clinical scenario and a peripheral blood platelet threshold. **Methods:** A retrospective study was carried out, with the platelet count of the registry of quality control of platelet concentrates (PC), obtaining a total of 100. Age, sex, blood group, and peripheral blood platelets were compared with donors not included in quality control. The sum of the platelet count of all possible combinations of the 100 PCs was obtained for the 2-3 PCs scenarios and the 4-8 PCs scenarios, a simulation of 1,000,000 iterations with random sampling without replacement and the sum of the platelet count of the combinations obtained was performed. The proportion of successful doses in the distribution was obtained according to the number of PCs. **Results:** No statistically significant difference was found between donors included in quality control and those not included. The probability of administering a dose of $\geq 1.5 \times 10^{11}$ platelets is 97.33% and 99.99% for 3-4 PCs, respectively. **Conclusions:** This study may be useful for the physician who indicates PC for prophylactic purposes, using an appropriate number of PCs, and optimizing the available inventory.

Keywords: Platelet concentrate. Platelet dose. Platelet prophylactic use.

Resumen

Introducción: La transfusión de plaquetas con fines profilácticos o terapéuticos es una práctica común. El desenlace evaluado en el uso de plaquetas con fines profilácticos ha sido la prevención del sangrado clínicamente significativo. Las guías de transfusión recomiendan el uso de transfusión plaquetaria con fines profilácticos en función del escenario clínico y un umbral de plaquetas en sangre periférica. **Métodos:** Se realizó un estudio retrospectivo, con el conteo plaquetario del registro del control de calidad de los concentrados plaquetarios (CP), obteniendo un total de 100. Se comparó la edad, sexo, grupo sanguíneo y plaquetas de sangre periférica con donadores no incluidos en el control de calidad. Se obtuvo la suma del conteo plaquetario de todas las combinaciones posibles de los 100 CP para el escenario de 2 y 3 CP, para los escenarios de 4-8 CP, se realizó una simulación de 1,000,000 de iteraciones con muestreo aleatorio sin reemplazo y suma del

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Date of reception: 10-05-2022
Date of acceptance: 18-07-2022
DOI: 10.24875/RMU.22000038

Available online: 20-10-2022
Medicina Universitaria. 2022;24(3):107-113
www.medicinauniversitaria.org

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conteo plaquetario de las combinaciones obtenidas. Se obtuvo la proporción de dosis exitosa en la distribución según el número de CP. **Resultados:** No se encontró diferencia estadísticamente significativa entre los donadores incluidos en control de calidad y los no incluidos. La probabilidad de administrar una dosis $\geq 1.5 \times 10^{11}$ plaquetas es de 97.33% y 99.99% para 3 y 4 CP, respectivamente. **Conclusiones:** Este estudio puede ser de utilidad para el médico que indica CP con fines profilácticos, utilizando una cantidad apropiada de CP y optimizando el inventario disponible.

Palabras clave: Concentrado plaquetario. Dosis plaquetaria. Uso profiláctico de plaquetas.

Introduction

Platelet transfusion for prophylactic or therapeutic purposes is a common practice. It is estimated that approximately 67% of platelet use goes to patients with hematology malignancies. Platelet transfusion can be performed through a product obtained by single donor apheresis (SDAP) or platelet concentrate obtained by fractionation of whole blood (PC), which is usually pooled in groups of 4-6 units¹. Although it is a debated topic, the use of SDAP has potential benefits, such as a lower risk of transfusion-transmitted infections (mainly bacterial), a lower risk of alloimmunization, and a greater number of platelets administered. Its implementation has not been universal, being used in some sites widely (such as the USA), but in other sites, many European centers mainly use PC pools². An important factor about universally implementing SDAP is cost, which is often considered higher than PC pool. It is difficult to provide an exact figure of the cost that the universal use of SDAP represents since local (institutional), regional, and commercial factors influence it, and there are even doubts about whether the use of SDAP for the prevention of adverse reactions is cost effective³.

The outcome evaluated in using platelets for prophylactic purposes has been the prevention of clinically significant bleeding, defined as bleeding ≥ 2 of the World Health Organization (WHO) classification. Several societies have issued a clinical guide for platelet transfusion, including the Association for the Advancement of Blood and Biotherapies (formerly named the American Association of Blood Banks, AABB)⁴, the British Society for Haematology (BSH)¹, and the American Society of Clinical Oncology (ASCO)⁵, which are based on a systematic review of the literature and recommend the use of platelet transfusion for prophylactic purposes depending on the clinical scenario and a peripheral blood platelet threshold. All of them agree with the recommendations for the platelet prophylactic use in treatment-induced hypoproliferative thrombocytopenia, considering a transfusion threshold $< 10,000$ platelets/ μL .

Regarding the standard platelet dose, the platelet unit refers to a unit of SDAP or a pool of 4-6 PCs (PCP), which contain between $3\text{-}4 \times 10^{11}$ platelets and is considered the standard dose. The AABB guideline recommends transfusion at a low dose (half a platelet unit, $1.5\text{-}2 \times 10^{11}$ platelets) or standard dose (platelet unit). It does not recommend higher doses, as low and standard doses are equally effective for preventing clinically significant bleeding⁴. The efficacy of the platelet dose has been evaluated by the dose administered per body surface area [BSA] ($1.1 \times 10^{11}/\text{m}^2 \pm 25\%$, low dose; $2.2 \times 10^{11}/\text{m}^2 \pm 25\%$, medium dose; $4.4 \times 10^{11}/\text{m}^2 \pm 25\%$, high dose)^{6,7}, and considering a BSA of 1.79m^2 in adults, the low dose is equivalent to $2 \times 10^{11} \pm 0.5 \times 10^{11}$ platelets and a medium dose to $3.9 \times 10^{11} \pm 1 \times 10^{11}$ platelets⁷.

The number of platelets in the platelet unit depends on several factors, including the type of fractionation, being higher in a buffy coat (BC) than in platelet-rich plasma (PRP), the resting time of whole blood before fractionation by the BC method and donor baseline platelet count (which, in turn, is higher in females)^{3,8,9}.

Enumerative combinatorics is the science of counting; its field of study includes combinations, which is the selection of a certain number of items from a set, regardless of the selection order, unlike permutation^{10,11}. Because obtaining the combinations of large sets can be computationally expensive, it can be approximated by a Monte-Carlo simulation, a type of simulation based on repeated random sampling closely related to random experiments¹². Hoeltge et al.¹³ used the mean and standard deviation to calculate the probability of administering 3×10^{11} platelets in a pool of 4-5 PCs, assuming a normal distribution of the dose sum, and subsequently performed a Monte-Carlo simulation of 100 iterations to validate the theoretical calculation.

The objective of this study is to approximate the distribution of the platelet dose according to the number of PCs administered, using combinatorics or a simulation and the data of the platelet count in the PC for the probability of achieving an appropriate dose, be it low or standard.

Material and Methods

Platelet concentrates method and sample

A retrospective study approved by the Ethics and Research Committee (registration code: PC21-00002) was carried out at the Blood Bank of the Department of Clinical Pathology of the “Dr. José E. González” University Hospital. The informed consent requirement was omitted as it was considered a risk-free study.

PCs were obtained from whole blood by the BC fractionation method. Whole blood was obtained in Grifols CPD-SAG MANNITOL bags, with quadruple bags and top and bottom system. After collecting whole blood, the unit of whole blood remains at rest for 1 h at room temperature. Then, centrifugation is carried out at 3500 rpm for 14 min at 22°C (Beckman Coulter J6-MI or Presvac DP 2065R centrifuge), obtaining erythrocyte concentrate, plasma, and BC using a semi-automated separator (Grifols Fractiomatic Plus 2). The BC rests for 2-6 h at room temperature. Subsequently, the BC is centrifuged at 1000 rpm at 22°C for 6 min, after which the PC is obtained through a semi-automated separator. The platelet count per PC was calculated by the product of the volume measured in microliters for each PC and the platelet count per microliter, which was obtained by taking an aliquot of PC which was diluted 1:5 with the Cell-Dyn Emerald (Abbott) analyzer diluent, in which said count was made. The platelet count was obtained from the quality control record (between January 20, 2020 and October 28, 2020), taking a sample of 100 PCs. It was carried out by randomly choosing PCs from the inventory available for clinical use before the end of their shelf life (≤ 5 days)¹⁴.

Representativeness of the sample concerning the donor population

To evaluate the representativeness of the platelet count obtained in the quality control concerning the donor population, data on age, blood group, sex, and base platelet count in hematic cytometry (obtained with a Cell-Dyn Emerald [Abbott] analyzer) were obtained from the donors of the PCs included in the quality control. The same data were obtained from donors whose PCs were not chosen randomly for quality control during the period from January 7, 2020 to August 31, 2020.

Platelet dose distribution according to the administration of multiple PCs

The distribution of the administration of n platelet concentrates was obtained by combinatorics or

approximated by simulation. Since the combinations of 2-3 platelet concentrates were 4950 (${}_{100}C_2$) and 161,700 (${}_{100}C_3$), respectively, they were obtained using all possible combinations and the sum of the platelet count of each possible combination; in the case of four PCs or more, due to the number of combinations (${}_{100}C_4=3,921,225$, ${}_{100}C_5=75,287,520$), the distribution was approximated using a Monte-Carlo simulation with 1,000,000 iterations, with random sampling without replacement of n elements (4, 5, 6, 7, and 8) of the platelet count obtained by quality control, obtaining the sum of the combinations of each iteration and using the Mersenne-Twister method to generate random numbers.

Probability of successful dose in the administration of multiple PCs

To evaluate the probability of a successful dose according to the amount of PCs administered, in the case of adults, a successful dose of 1.5×10^{11} and 3.0×10^{11} platelets was chosen, the first being a low dose, considered safe, and the second the standard dose. For pediatric patients, successful doses of 1.1×10^{11} platelets/m² (low dose) and 2.2×10^{11} platelets/m² (medium dose) were used; the body surfaces of male children aged 1, 3, 6, and 10 years were considered, using the DuBois-DuBois formula for their calculation⁶. For the height and weight data of 1-3 years old, the 50th percentiles of the WHO child growth standards curve were used¹⁵. For the data of children 6-10 years old, mean weight and mean height reported by Ferreira-Hermosillo et al. were used¹⁶. The use of the anthropometry of male children was chosen because the difference concerning girls is low, and the results obtained can be generalized to girls since they would be receiving the same or a slightly higher dose. To obtain the distribution of administered platelets per m² of the body surface, the distributions of 2, 3, and 4 PCs were scaled by multiplying the distribution vector by the inverse of the body surface of each age. The probability of a successful dose in each scenario (definition of a successful dose and amount of PC administered) is calculated by means of the proportion of combinations whose result is equal to or greater than the target dose, expressed in percentage terms (Formula 1).

$$P(\text{administered dose} \geq \text{target dose} | nPC \times 100) \quad (1)$$

Statistical analysis

The distribution of quantitative variables (baseline platelet count, platelet count in PC, and age) was evaluated by the Shapiro–Wilk test. They are described as mean and standard deviation (SD) or median and interquartile range depending on whether or not normal distribution is rejected. Categorical variables are described by percentage proportion. The distributions of the doses according to the number of PCs are described by percentiles (2.5, 50, and 97.5). For the difference of quantitative variables between donors included in quality control and the general population of donors, the Mann–Whitney U test or Welch’s t-test is used, as applicable. A Chi-square test or Fisher’s exact test is performed for the difference of categorical variables, as applicable. A statistically significant result of $p < 0.05$ is considered to reject the null hypothesis. Statistical data and the simulations were analyzed with R (version 4.0.5) and RStudio Desktop (version 1.4.1106) software.

Results

In the case of the distribution of the platelet count in PC, normality is not rejected (Shapiro–Wilk $p = 0.077$), obtaining an estimate of the mean of 0.755×10^{11} with SD 0.25×10^{11} . For age and baseline platelet count in hematic cytometry, normality is rejected (Shapiro–Wilk < 0.001). **Table 1** shows the characteristics of the donors included in the quality control and those not included in the quality control (the latter being a total of 1,586 donors). No statistically significant difference was found in sex, blood group, age, and platelet count in peripheral blood in both groups.

The dose distribution for 3 PCs has a median of 2.24×10^{11} (2.5-97.5 percentiles of $1.49-3.15 \times 10^{11}$) platelets; the distribution for four PCs, a median of 3.0×10^{11} (2.5-97.5 percentiles of $1.49-3.15 \times 10^{11}$) platelets. In the case of three PCs, the probability of successfully administering a dose of $\geq 1.5 \times 10^{11}$ platelets is 97.33%. In the case of 4 PCs, it is 99.99%. The probability of administering a dose of $\geq 3.0 \times 10^{11}$ platelets is 92.70% in administering five CP and 99.77% for six CP. **Table 2** details the probability of success of the administered dose, median, and quartiles for the distribution according to the number of platelets. **Figures 1-3** graphically show the dose distribution in the administration of different numbers of CP. In the case of pediatric patients, a dose of $\geq 1.1 \times 10^{11}/m^2$ is achieved with 2 CP in 100% of 1 year old and 99.88% in 3 years old. For the

Table 1. Differences between group of donors included and not included in PC quality control (PCQC)

	PCQC	Not-PCQC	p
Sex (Female)	20.0%	24.5%	0.37 ^a
ABO blood type			
O	63.0%	68.2%	
A	24%	31.8%	
B	13%	7.0%	
AB	0.0%	0.9%	
			0.17 ^b
Rh (+)	98%	95.8%	0.46 ^b
Age (years)	34.5 (25-42)*	34 (27-42)*	0.76 ^c
Platelet count (K/ μ L)	245.5 (200.7-282.5)*	249 (211-290)*	0.34 ^c

^aChi-squared test; ^bFisher exact test; ^cMann–Whitney U test; *Median (intercuartil range).
PC: platelet concentrate.

Table 2. Probability of administering target dose according to the number of PCs in adults (BSA 1.79 m²)

PCs	Probability of administering dose		Platelet dose distribution $\times 10^{11}$
	$\geq 1.5 \times 10^{11}$ (%)	$\geq 3 \times 10^{11}$	Median (percentile 2.5-97.5)
2	49.35	0	1.49 (0.89-2.26)
3	97.33	5.06	2.24 (1.49-3.15)
4	99.99	50.06	3.0 (2.12-4.03)
5	100	92.70	3.76 (2.76-4.90)
6	100	99.77	4.51 (3.24-5.74)
7	100	99.99	5.27 (4.09-6.58)
8	100	100	5.57 (4.76-7.41)

BSA: body surface area; PC: platelet concentrate.

6-10-year-old scenarios, with three CP, a dose of $\geq 1.1 \times 10^{11}/m^2$ is achieved in 99.99% and 99.87%, respectively. The different scenarios are presented in detail in **table 3**. Taking into account that the studies that have compared the efficacy of low versus medium doses accept a variation of $\pm 25\%$, that is, a lower limit of 0.825×10^{11} platelets for the low dose, with two PCs, it is reached in 100% of the 1-3-year scenarios, 99.40% of the 6-year scenarios and 97.43% of the 10-year scenarios; in the case of three PCs, said lower limit is reached in 100% of cases in the four scenarios proposed.

Table 3. Probability of administering the target dose according to the number of PCs in children

		Years (weight, height)	1 (9.5 kg, 76 cm)	3 (14.5 kg, 96 cm)	6 (25.6 kg, 120 cm)	10 (31.78 kg, 1.33 cm)
PC number		BSA (m ²)	0.43	0.62	0.92	1.08
2	Probability of successful dose ($\times 10^{11}$)	$\geq 1.1/m^2$	100%	99.88%	93.17%	81.20%
		$\geq 2.2/m^2$	96.04%	66.26%	7.94%	1.25%
	Percentile distribution 50 (2.5-97.5), $\times 10^{11}$		3.47 (2.07-5.25)	2.45 (1.46-3.70)	1.62 (0.97-2.46)	1.38 (0.82-2.09)
3	Probability of successful dose ($\times 10^{11}$)	$\geq 1.1/m^2$	100%	100%	99.99%	99.87%
		$\geq 2.2/m^2$	99.99%	99.27%	69.98%	38.23%
	Percentile distribution 50 (2.5-97.5), $\times 10^{11}$		5.22 (3.47-7.33)	3.68 (2.44-5.17)	2.44 (1.62-3.34)	2.08 (1.38-2.92)
4	Probability of successful dose ($\times 10^{11}$)	$\geq 1.1/m^2$	100%	100%	100%	100%
		$\geq 2.2/m^2$	100%	100%	98.64%	90.94%
	Percentile distribution 50 (2.5-97.5), $\times 10^{11}$		6.98 (4.93-9.38)	4.92 (3.48-6.61)	3.26 (2.31-4.39)	2.78 (1.96-3.74)

BSA: body surface area; PC: platelet concentrate.

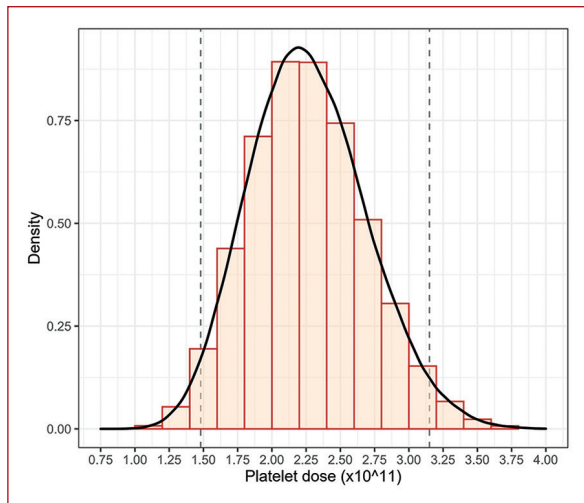


Figure 1. Histogram and density plot of platelet dose in 3 platelet concentrates. Dashed vertical lines: percentiles 2.5 and 97.5.

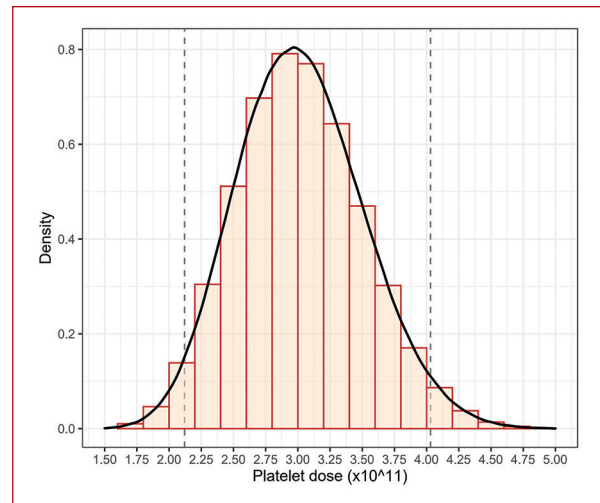


Figure 2. Histogram and density plot of platelet dose in 4 platelet concentrates. Dashed vertical lines: percentiles 2.5 and 97.5.

Discussion

This study found a mean platelet count of 0.755×10^{11} in PCs. The standard deviation was 0.25×10^{11} . The mean is lower than that of another study analyzing BC-PC (0.876×10^{11} and SD 0.29×10^{11})¹⁷ and similar to that reported by Singh et al. (in PRP-PC mean 0.76×10^{11} , SD 0.297×10^{11} ; BC-PC mean 0.73×10^{11} , SD 0.298×10^{11})¹⁸. Since we found no statistically significant difference between the characteristics of the

donors from whom the sample for the study comes and the donors not included in the quality control, we consider that the distribution of the sampled donors for the estimation of the different distributions of the doses administered are representative of the general population of donors and the results obtained can be generalized to the PC inventory in clinical use at our center.

In the adult setting, a dose equivalent to half a platelet unit is achieved with three or four PCs in most cases, and if one platelet unit is required, it is achieved

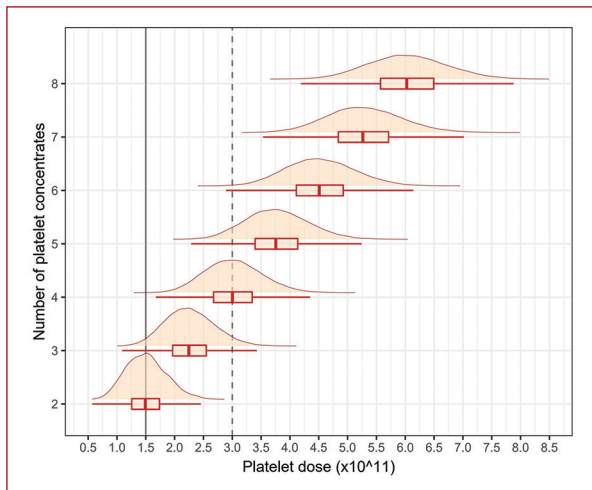


Figure 3. Density and box plot of platelet dose in 2-8 PCs. Continuous vertical line 1.5×10^{11} ; dashed vertical line 3.0×10^{11} .

with five or six PCs in most cases. On the other hand, in the pediatric patient scenario, the lower limit of the low dose (0.825×10^{11}) is reached with two CP in most cases. Although there are defined recommendations for specific clinical scenarios in the platelet transfusion clinical practice guidelines, individual scenarios may be presented where the physician decides on a target dose higher than low (either half a platelet unit or $1.1 \times 10^{11}/m^2 \pm 25\%$) or standard doses so that these distributions can be a guide.

The benefit of the minimum necessary administration of PCs is, on the one hand, due to the decrease in transfusion reactions due to platelet components, which is 1/14 for febrile reaction, 1/50 for allergic reaction, and 1/75,000 for bacterial sepsis, to name a few of the most common⁴. On the other hand, there is the optimization of resources since it is a product with a highly variable inventory. It has been observed that in the case of administration of low versus medium and high doses with prophylactic intention, the total administration of platelets is lower in the case of low doses (median of 9.25×10^{11} , 11.25×10^{11} , and 19.63×10^{11} for low, medium, and high dose, respectively), although it requires more frequent administration⁶.

Conclusions

This study shows the distribution of the administered doses according to the number of PCs in a representative sample of the general population of donors. It can be

useful for the physician who indicates PC for prophylactic purposes according to the recommendations of international guidelines, using an appropriate number of PCs according to each clinical scenario, helping to optimize the available inventory, and reducing the risk of transfusion-associated reactions. It is a simple method that can be performed on any personal computer using the center's data to estimate the probability of a successful dose.

Funding

No funding to declare.

Conflicts of interests

The authors declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects: The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data: The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent: The authors have obtained approval from the Ethics Committee for the analysis and publication of routinely-acquired clinical data, and informed consent was not required for this retrospective observational study.

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