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Quality analysis of blood components obtained by automated buffy-coat layer removal with a Top & Bottom system (Optipress ®II)

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ABSTRACT

Background and Objectives. **There are Council of Europe recommendations for the quality of blood components. We analyzed the quality of blood components processed by a *top & bottom* system (Optipress® II), the routine method used in our blood bank, to test whether the components reached the recommended quality.**

Design and Methods**. Blood was collected in triple CPD-SAGM bags (Optipac® Baxter). Whole blood (WB) was centrifuged at 4,158 g for 14 min before separation by an automated top & bottom system (Optipress® II). Platelet concentrate (PC) was prepared by pooling four isogroup buffy-coat (BC) units before low-speed centrifugation, and transferring the supernatant (4 BC-PC) to a 5-day storage bag (PL732, Baxter). An alternative approach involved PC preparation from a single BC unit by adding approximately 70 mL of plasma before centrifugation, followed by transfer of the platelet concentrate (1BC-PC) to a 300 mL Teruflex®, transfer bag. Both 4 BC-PC and 1 BC-PC were stored in a flat agitator at 22°C for up to 5 days after collection. Cell counts were determined, along with hemoglobin and hematocrit in a Sysmex K-800 cell counter. The pH was determined on day 5 at 22°C. Weights were measured and volumes were calculated based on specific gravity. Statistical analyses were carried out using the Kolmogorov-Smirnov test as a normality distribution test, the t-test for parametric values and Wilcoxon's test as a non-parametric test. Statistical significance between samples was considered to have been reached when $p<0.05$.**

Results. **The best parameters for configuring the system were: strength 25; BC volume 33-55; level of BC 5.5. Red blood cell (n = 1,434) volume was 279±20 mL, with 54.92±7.16 g of hemoglobin. More than 96% of units had fewer than 1.2×10^9 white blood cells. Fresh plasma volume (n = 803) averaged 279±19 mL, with a white blood cell contamination of fewer than 0.1×10^9/L in all samples examined (n = 23). Platelet recovery in BC was 92±9% of platelets present in WB; the percentage of removed leukocytes was 74±10%, and between 13 and 15% of RBCs were lost in the BC (95% confidence interval). The BC volume (n = 1,037) fitted the target volume of 60 mL, except for some devices, when Optipress II® lost the configuration for this parameter. Of 4 BC-PCs 80.3% yielded more than 0.6×10^{11} platelets per unit, whereas this criterion was only met by 59.7% of 1 BC-PCs, and a greater proportion of 1 BC-PCs (58.8%) showed pH values within the range of 6.5-7.4 after 5 days of storage in comparison with 4 BC-PCs (44.25%).**

Interpretation and Conclusions. **Optipress II® provides standardized, leukocyte-poor blood components. Council of Europe requirements were met in a large percentage of red-cell concentrates, with less than 92 and 74% of the original platelets and leukocytes, respectively, and a small hemoglobin loss per unit. The system gave an optimal yield in terms of plasma volume. The top & bottom technique allowed us to reduce the number of blood units per platelet concentrate from 6 to 4 units, with similar platelet yields compared with traditional procedures. Nevertheless, the storage conditions must be improved to satisfy all Council of Europe requirements for platelet concentrates.**

Key words: automatic blood separation, blood components, top & bottom technique

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Blood fractionation systems based on leukocyte-platelet buffy-coat (BC) extraction use a number of different technical approaches. The *Top & Bottom* technology was initially described by Högman *et al*.,[1] and its efficacy in terms of yield and purity of blood components obtained has been well established. Indeed, the method has not been bettered by any other blood fractionation system to date.

Blood fractionation classically commences with the separation of the platelet-rich plasma (PRP) fraction from whole blood (WB) by low-speed centrifugation. Subsequent high-speed centrifugation of PRP in turn yields the corresponding platelet concentrate (PRP-PC).[2] In contrast, fractionation involving BC extraction via the *Top & Bottom* technique is based on blood component separation by initial high-speed centrifugation of WB in sealed triple or quadruple bag systems, followed by simultaneous extraction of fresh plasma (FP) at the top, and the red blood cell (RBC) concentrate at the bottom, of the respective satellite bags that constitute the blood extraction bag system – keeping the leukocyte-platelet buffy coat layer stable throughout the process within the original extrac-

tion bag. The BC component in turn yields the platelet concentrate (PC-BC) after low-speed centrifugation and removal of the plasma from the PRP.

The *Top & Bottom* approach allows a marked reduction in leukocyte contamination of the different blood components[3] – a fact that contributes to diminishing the incidence of non-hemolytic febrile transfusional reactions. The RBC loss has been reported to be greater than with the classical method.[4] However, adequate adjustment of the centrifugation and fractionation system configuration parameters can mitigate such losses, affording maximum yield from each donation and the production of blood components of increased quality.[5,6]

In our center we have recently substituted a conventional fractionation method involving quadruple WB bags by a fractionation system based on *Top & Bottom* technology (Optipress® II). With the aim of establishing the efficacy of the new technique, we conducted a quality control study of the blood components derived from routine blood fractionation with this new method in our blood bank over a two-year period, comparing the results obtained with the Council of Europe (CE) quality recommendations for the production and storage of blood components.[7]

Design and Methods

Blood component production and storage

Blood donations were extracted in compliance with good clinical practice, using triple bags, Optipac® CPD-SAGM system, R7322 and RGR7335 (Fenwal, Baxter S.A. Maurepas, France). The WB units were refrigerated at 22±2ºC following extraction, employing insulating containers and butane-1,4-diol plates at 4ºC until fractionation within 18 hours of extraction. All units were subjected to high-speed centrifugation (4,158 g, 14 min, 22ºC) in Cryofuge 6000, 8000 and 8500 centrifuges (Hereaus Sepatech, GmbH, Germany), to separate the three phases, producing a clearly defined leukocyte-platelet BC layer.

Automatic fractionation was carried out using *Top & Bottom* technology (Optipress® II; Fenwal, Baxter S.A. Maurepas, France). Briefly, this equipment consists of a columnar series of optical detectors located on the inner surface of a mobile press that applies pressure to the bag of centrifuged blood. The system detects fluctuations in BC level during the separation process, thereby causing a pincer/sealing system to open or close, and facilitating plasma extraction at the top, and red cell extraction at the bottom, of the respective bags – while maintaining the BC layer constant between preconfigured optimal values. Continuous control of the pincer aperture keeps the BC layer constant at the preset level until completion of the process, marked by a pre-established BC residual volume.

Following primary separation, the FP was rapidly frozen in a vapor-phase N_2 freezer at –80ºC (Frigothermic, A.O.L, S.A., Barcelona, Spain) and stored in an electric freezer at –35ºC. The RBC concentrate was in turn directly stored in the refrigerator at 4±2ºC until being sent to other hospital centers. The BC were stored at rest at 22±2ºC for at least two hours after primary fractionation, and afterwards were either discarded or used for PC preparation.

Platelet concentrate (PC) was obtained in two different ways: four isogroup BC units were pooled by a sterile connector device TSCD SC-201 (Terumo Corporation, Tokyo, Japan) before low-speed centrifugation (1,040 g, 9 min, 22ºC) using supports designed to keep the bag firm during the process, and the PRP supernatant (4 BC-PC) was transferred by a manual plasma removal device to a 1,000 mL, PL732 bag (R2238, Fenwal, Baxter, S.A.) and stored on a flat agitator at 60 cycles/min and 22±2ºC until use within 5 days of extraction. The alternative approach involved PC preparation from a single BC unit by adding approximately 70 mL of FP before centrifugation (321 g, 6 min, 22ºC), followed by manual transfer of the platelet concentrate (1 BC-PC) to a 300 mL (Teruflex, BBT030CM, Terumo Corporation) transfer bag, under the same conditions as those used for the previous method.

Sampling and determinations

WB units were randomly selected, along with RBC concentrates, BC and FP units for which no incidents had been recorded during either extraction or fractionation. The selected units were weighed and sampled before freezing in the case of FP, by puncture following homogenization. The volumes were calculated according to weight and estimated density for WB in CPD, RBC concentrate in SAGM, BC (1.058 g/mL) and FP (1.026 g/mL). Cell counts were determined, along with hemoglobin and hematocrit in a Sysmex K-800 (TOA Medical Electronics Co., Ltd, Japan) cell counter. In addition, a Nageotte chamber was used for confirming white blood cell (WBC) counts in FP. The pH was determined at the end of the storage period at 22ºC using a Crison 2000 pHmeter (Crison Instruments, S.A. Barcelona, Spain).

Statistical analysis

The SPSS statistical package was used for the descriptive statistical study. The Kolmogorov-Smirnov test was employed as a normality distribution test, a t-test for parametric values and Wilcoxon's test as a non-parametric test. Statistical significance between samples was considered to have been reached when $p<0.05$.

Results

The optimum process configuration, established individually for each machine before routine use, was as follows: strength 25; BC level 5.5; BC volume between 33-55 mL to obtain 60 mL.

The WB samples included in the study exhibited a normal distribution in terms of volume, cell count, hemoglobin and hematocrit. All the WB units had hemoglobin levels above 45 g (mean ± standard deviation (SD): 61.92±6.91 g), with a mean volume (including CPD volume) of 516±16 mL. The results of the WB determinations are shown in Table 1.

The mean RBC concentrate volume was 279±20 mL, and the mean hemoglobin contents were over 43 g in 96.3% of cases. Only 8 units contained less than 43 g of hemoglobin, coinciding with hematocrit values of under 50%. The mean percentage recovery of hemoglobin in the RBC concentrates was over 84%. As far as regards leukocyte contamination of

Table 1. Volume and cell counts per whole blood unit.

	Vol. (mL) with CPD	*WBC (x10⁹)*	*Plt (x10¹¹)*	*RBC (x10¹²)*	*Htc (%)*	*Hb (g)*
Mean±SD	516±16	3.64 ±0.86	0.96±0.24	2.02±0.24	35.87±3.48	61.92±6.91
Range	468-557	2.11-5.92	0.55-1.67	1.63-2.47	29.1-41.2	48.6-76.22
95% CI	515-517	3.37-3.90	0.89-1.03	1.94-2.09	34.79 -36.94	59.79-64.05
n	802	43	43	43	43	43

Mean, standard deviation, range, and 95% confidence interval are shown. Vol: volume; WBC: leukocytes; RBC: erythrocytes; Hct: hematocrit; Hb: hemoglobin; Plt: platelets.

Table 2. Volume and cell counts per unit of red blood cell concentrate.

	Vol (mL) with SAGM	*WBC (x10⁹)*	*RBC (x10¹²)*	*RBC recovery (%)*	*Hct (%)*	*Hb (g)*	*Hb recovery (%)*
Mean±SD	279±20	0.50±0.33	1.81±0.23	84.09±5.46	60.87± 4.49	54.92±7.16	84.35±5.36
Range	212-344	0.00-2.97	1.19-2.62	76 – 98	49.9-87.2	36.31-84.87	75–98
95% CI	278–280	0.48-0.53	1.79-1.83	82.41- 85.77	60.53-60.21	54.38-55.46	82.7-86.0
n	1,434	672	672	43	672	672	43
% within CE criteria		96			96.6	96.3	

Mean, standard deviation, range, and 95% confidence interval are shown. Vol.: volume; WBC: leukocytes; RBC: erythrocytes; Hct: hematocrit; Hb: hemoglobin; Plt: platelets

Table 3. Volume and cell counts per liter of fresh plasma.

	Vol (mL)	*WBC (x10⁹/L) Nageotte chamber*	*RBC (x10⁹/L)*	*Plt (x10⁹/L)*
Mean±SD	279±19	0.01±0.02	0.00±0.01	9.32±5.44
Range	226-336	0.00-0.06	0.00-0.06	1.00–25.00
95% CI	278-288	0.00-0.02	0.00-0.06	7.87–10.76
n	803	23	57	57
% within CE criteria		100	82.5	100

Mean, standard deviation, range, and 95% confidence interval are shown. Vol: volume; WBC: leukocytes; RBC: erythrocytes; Plt: platelets.

the RBC concentrates, 96% of the units had fewer than 1.2×10^9 leukocytes – the mean count being considerably lower. The results of the RBC concentrate determinations are shown in Table 2.

The mean FP volume obtained was 279±19 mL, with a mean leukocyte count per liter of under 0.1×10^9 in 96% of the cases. This figure was below the cell counter discrimination threshold; consequently, 23 cases were subjected to hemocytometer counting, yielding a maximum of 0.06×10^9 leukocytes per liter. The platelet contents were in turn under 50×10^9/L in all cases, and 82.5% of all units had fewer than 6×10^9 red cells (Table 3).

The mean volume of the extracted BC layer was 57±5 mL. It should be pointed out that of the 1,037 units studied, substantial variations in BC volume were recorded only in 69 cases (6%), which were always found to be units processed by machines that had lost their configuration for this particular parameter as a result of technical failure (Figure 1). The remaining plasma volume per BC unit yielded a mean value of 32±4 mL with a mean platelet content of 0.88± 0.23×10^{11}; this implies that more than 90% of the platelets present in a given WB unit were left in the original extraction bag following primary fractionation. The loss of hemoglobin in the BC only ranged between 3.23-10.5 g, with 14±2% of red cells (Table 4).

The 4 BC-PC preparations yielded a mean platelet count of $0.68\pm0.12\times10^{11}$ platelets per BC unit; as a result, 80.3% of the units were within the limits recommended by the CE. The mean platelet count in the case of the 1 BC-PC units was slightly lower (see Tables 5 and 6). However, dispersion was greater than in the case of the 4 BC-PC samples, as a result of which only 59.7% of the 1 BC-PC units had more than 0.6×10^{11} platelets (p=0.001). The leukocyte count was under 0.05×10^9 in 64.8% of the 4 BC-PC units. In contrast, 84.1% of the 1 BC-PC units exhibited a leukocyte count of under 0.05×10^9 per unit.

The CE recommends retaining 50 mL of plasma per 0.6×10^{11} platelets in PC units, corresponding to a volume of 0.83 mL/10^9 platelets or more. Both the 4 BC-PC and 1 BC-PC units satisfied this criterion with values far above the recommended minimum: 1.31±0.28 mL/10^9 and 1.57±0.60 mL/10^9 platelets, respectively (p<0.001).

The pH values recorded in the PC units after 5 days of storage showed a marked deviation from the values recommended by the CE (Tables 5 and 6). Only 44% of the 4 BC-PC units versus 59% of the 1 BC-PC units had pH values in the range of 6.5 to 7.4 – with a clear tendency towards pH readings under 6.5 by day 6 of storage (in 52% of the 4 BC-PC versus 38% of the 1 BC-PC units; p<0.001). On the other hand, only 3% of either unit type showed pH values of over 7.4.

Discussion

Blood fractionation systems that include removal of the buffy-coat (BC) layer have evolved considerably in the past two decades, with a shift from manual extraction procedures to fully automated systems that allow standardized extraction and contribute to

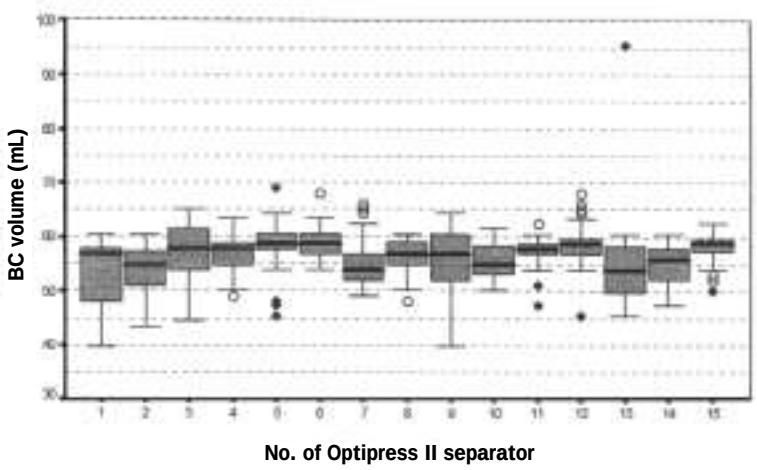

Figure 1. Box diagram showing BC volume (in mL) obtained with each Optipress® II separator (numbered 1 to 15). The height of each box corresponds to the interquartile space amplitude (d); the thick tracing within is the median, and the outliers or external segments represent 1.5 times the interquartile space amplitude. The circles symbolize the atypical values (over 1.5 x d), while the rhombi represent the extreme values (over 3xd). Machines 1, 3, 9 and 13 produced BC units with the greatest volume deviations (greater d). Separator number 5 produced an increased number of extreme values. All these machines were found to have temporarily lost their configuration for the parameter "BC volume", due to technical failure.

Table 4. Volume and cell counts per buffy-coat unit.

	Vol (mL)	*Plt ($x10^{11}$)*	*Plt recovery (%)*	*WBC ($x10^9$)*	*WBC recovery (%)*	*RBC ($x10^{12}$)*	*RBC recovery (%)*	*Hb (g)*	*Htc (%)*
Mean±SD	57.5± 4.7	0.88±0.23	92±9	2.61±0.73	74±10	0.26±0.04	14±2	8.13±1.04	43.84±4.28
Range	40-95	0.19- 1.52	66-99	0.64- 4.65	53-95	0.1-0.35	10 -18	3.23-10.5	17.2-52.6
95% CI	57.2-57.8	0.84 -1.04	89-95	2.46-2.99	69-77	0.26-0.29	13 -15	7.96-8.30	42.18-44.79
n	1037	142	31	142	31	142	32	142	142

Mean, standard deviation, range, and 95% confidence interval are shown. Vol: volume; WBC: leukocytes; RBC: erythrocytes; Hct: hematocrit; Hb: hemoglobin; Plt: platelets.

Table 5. Volume and cell counts in 4 BC-PC.

	Vol (mL)	*Vol /10^9 Plt*	*Plt in 4BCPC ($x10^{11}$)*	*Plt/unit ($x10^{11}$)*	*WBC/unit ($x10^9$)*	*pH*
Mean±SD	346±23	1.31±0.28	2.73±0.47	0.68±0.12	0.06±0.08	6.51±0.46
Range	269 – 430	0.85-2.94	1.09-3.97	0.27-0.99	0.00-0.63	5.8-7.59
95% CI	343 – 349	1.27-1.34	2.68-2.79	0.67-0.69	0.05-0.07	6.46-6.57
n	325	325	325	325	325	325
% within CE criteria		100		80.3	64.8	44.25

Mean, standard deviation, range, and 95% confidence interval are shown. Vol: volume; WBC: leukocytes; Plt: platelets.

good laboratory practice in the preparation of blood components.[8] The inclusion of quality control systems in blood banks has made it necessary to adopt working methods that guarantee reproducible obtainment of the blood components; this in turn obliges quality analyses of the products obtained on a routine basis, with careful control of the processing procedures involved.

Extraction of the BC layer during the blood separation process constitutes a step towards obtaining blood components less contaminated by leukocytes. Leukocytes have adverse effects upon the storage and preservation of therapeutic blood products, can be a source of pathogenic micro-organism transmission (e.g., cytomegalovirus) and cause non-hemolytic febrile reactions.[9] At present, blood product leukocyte depletion is viewed as a therapeutic measure indicated for patients with a history of non-hemolytic febrile transfusional reactions, for it retards cytomegalovirus infection.[10]

The present study describes the quality of blood components produced on a routine basis since the introduction of *Top & Bottom* technology in our blood bank, and how this quality fulfils the quality criteria recommended by the Council of Europe (Table 7).

The fractionation method previously employed in our center included the use of automatic extractors operating with quadruple bag systems; following plasma removal, the BC layer was transferred to a satellite bag, retaining the RBC concentrate in the original extraction bag. SAGM was added to the latter following removal of the BC layer. Quality control analyses of blood components obtained with this method revealed greater leukocyte and platelet contamination of the RBC concentrate than after fractionation using the Optipress® II system. This was attributed to cell adherence within the original extraction bag in the course of press removal of the BC lay-

Table 6. Volume and cell counts in 1 BC-PC.

	Vol (mL)	*Vol /10⁹ plt*	*Plt in PC (x10¹¹)*	*WBC/unit (x10⁹)*	*pH*
Mean	91	1.57	0.64	0.03	6.69
SD	11	0.60	0.19	0.02	0.5
Range	51-126	0.71-5.45	0.22-1.26	0.00-0.17	5.75-7.70
95% CI	89-92	1.48-1.66	0.60-0.66	0.02-0.03	6.61-6.77
n	226	226	226	226	226
% within CE criteria		98.7	59.7	84.1	58.8

Mean, standard deviation, range, and 95% confidence interval are shown. Vol: volume; WBC: leukocytes; Plt: platelets.

er; as a result, platelet yield in the BC layer was less than 80%.[11] This difference in the BC separation method points to more effective platelet and leukocyte removal with the Optipress® II system, and allowed us to reduce (from 6 to 4) the number of BC units in the preparation of pooled platelet concentrates (PC) after installation of the *Top & Bottom* technology in our center.[12] As a result, the risk of recipient exposure to allogeneic mixtures is, to a certain extent, lessened.

In general, the results of the quality control analyses of routine fractionation with the Optipress® II system show a high degree of compliance with the CE recommendations. In effect, over 96% of the RBC concentrate units contained more than 43 g of hemoglobin, with a hematocrit of 50-70%, and a leukocyte count of under 1.2×10^9. It is estimated that the risk of transfusion-associated cytomegalovirus infection is avoided at fewer than 5×10^6 leukocytes – a figure achieved by using high-efficacy filters. It has recently been shown that the efficacy of such filters improves when used for RBC concentrates from which the BC layer has previously been removed.[13] Our data confirm this, for all the RBC concentrates filtered in our blood bank had fewer than 5×10^6 leukocytes per unit, and 94% had fewer than 1×10^6.

The reduction of leukocyte contamination of plasma to values of under 0.1×10^9/cells per liter was observed in all cases. In turn, the platelet presence was reduced to under 50×10^9/cells per liter in 100% of cases, and red cell count to fewer than 6×10^9/cells per liter in 83% of the plasma units analyzed. This is important, because low-leukocyte plasma fractions facilitate the viral photoinactivation to which fresh plasma units are presently subjected. On the other hand, as has been pointed out by Rider *et al.*,[14] the increased leukocyte depletion afforded by filters contributes to augment the efficacy of methylene blue viral inactivation, since this technique is only effective for viruses not associated with cells.

Eighty percent of the PC prepared by the pooling system contained over 60×10^9 platelets, compared with fewer than 60% of the PC units prepared by the 1 BC-PC single-bag technique. Leukocyte restriction to under 0.05×10^9 cells per unit was achieved in fewer than 65% of the 4 BC-PC units, but in more than 84% of the 1 BC-PC units. These results indicate that PC preparation by the pooling system affords increased standardization as regards the platelet count per unit ($p = 0.001$), since it reduces the individual variability in platelet count observed when PC is prepared from a single donation. However, this process minimizes recipient exposure to allogeneic mixtures; as a result, in our center 1 BC-PC units are only destined for pediatric use.

The poorest compliance with the CE recommendations was found for the pH value recorded at the end of storage, with about 40% and 60% compliance for the 4 BC-PC and 1 BC-PC units, respectively. Here again, the method employed for preparing PC seems to influence the quality of the units obtained ($p<0.001$); the 1 BC-PC procedure gave greater volume/platelet ratios than the 4 BC-PC method, and the latter consequently yielded pH values of under 6.5 in most cases. These results suggest that despite the optimum plasma volume present in both types of PC unit, the storage conditions need to be improved by using high permeability plastic materials to maintain the pH within the range recommended for preserving platelet viability throughout the duration of storage.[15]

On the other hand, the amount of plasma obtained with *Top & Bottom* technology reached optimum values (279±19 mL), thereby contributing to reduce the lack of self-sufficiency in plasma destined for the preparation of plasma components - a situation that has been reported both in our regional and at a national level.[16,17]

As far as regards RBC loss associated with *Top & Bottom* technology, our experience indicates that 13-15% (95% confidence interval) of red cells are lost in the BC layer. This figure decreases as the precision of the configuration parameters is increased. However, our results point to the need for strict checking of the equipment during routine operation, since minor adjustments in configuration can modify the volume and remaining cell contents in the BC units – thus adversely affecting

Table 7. Recommendations from the Council of Europe (4th edition).

	VoL (mL)	*Hb (g/unit)*	*Htc (%)*	*WBC*	*Plt*	*RBC*	*Required % compliance**
WB	450±10	Min. 45					100%
RBC		Min. 43	50-70	$< 1.2\times10^9$/U*			75%
FP				$< 0.1\times10^9$/L*	$< 50\times10^9$/L*	$< 6\times10^9$/L*	100%
PC	>50			$< 0.05\times10^9$/U*	$> 60\times10^9$/U*		75%

Required compliance in each blood component is shown. WB: whole blood; RBC: red blood cells; FP: fresh plasma; PC: platelet concentrate; Vol: volume; WBC: leukocytes; Hb: hemoglobin; Hct: hematocrit; Plt: platelets.

the blood products obtained (Figure 1).

The conclusions of the present study may be summarized as follows: i) routine utilization of the Optipress® II system yields blood components with a high degree of standardization and low cell contamination. The RBC concentrates obtained easily satisfy the CE recommendations, with elimination of over 70% of leukocytes and more than 90% of platelets present in whole blood, and produces minimum hemoglobin losses per unit; ii) the Optipress® II system improves the logistics of PC preparation, by reducing the number of BC units per pool and thus facilitating increased PC production; iii) PC unit storage may be improved by using high gas permeability bags that afford good platelet viability; iv) the fresh plasma volume per unit ranges from 278 to 288 mL (95% confidence interval), i.e., an optimum amount that contributes to reducing the lack of self-sufficiency in plasma components in our community; v) the use of automated systems requires strict monitoring of the configuration parameters in order to guarantee blood fractionation equipment reliability and efficacy.

Contributions and Acknowledgments

CH had main responsibility for all aspects of this study, carry out the laboratory work and wrote the paper. SB, IB, MDP contributed to analysis and interpretation of data. MAS and VM discussed the main points of the paper and critically revised it. AdM was responsible for the critical evaluation and final approval of this version. The order of authorship is in accordance with these contributions.

Disclosures

Conflict of interest: none

Redundant publications: no substantial overlapping with previous papers.

Manuscript processing

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Potential implications for clinical practice

- The Optipress® II system produces standardized, good quality blood products efficiently, thus reducing risks of micro-organism transmission and non-hemolytic febrile reactions in recipients, and increasing the self-sufficiency of blood banks in producing plasma components.

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