

# Prospective, Comparative Study Between Fully-Automated and Semi-Automated Whole Blood Processing Systems in a Colombian Blood Bank Center

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## Introduction

During the last years, blood bank centers are being more focused into evaluating multiple parameters from their processed blood products, as well as the different operating and processing systems, to optimize and maximize standardization, productivity and quality in all levels. Currently, the most used whole blood processing systems are the semiautomated (SABPS), that requires, at least, four different medical technologies, and the fully-automated (ABPS), that only requires one medical technology.<sup>[1][2][3][4]</sup>

## Objectives

The aim of this prospective study is to evaluate and compare quality and security parameters of final blood products processed using the SABPS versus the ABPS, maintaining the same whole blood processing protocols for each system and the same operating staff from Hospital Pablo Tobón Uribe Blood Bank Center, located in Medellín, Colombia.

## Materials and methods

In Hospital Pablo Tobón Uribe Blood Bank Center (Medellín, Colombia), from 20th to 24th November 2023, 80 whole blood bags (WBB) were included in the study.

40 WBB model “PB\*4BO456-ZOY” from Terumo Blood and Cell Technologies® (BCT) were processed with the SABPS. The devices used were the centrifuge model “DP-2065-R” from Presvac Systems®; and the separator model “T-ACE II®”, the sealer model “TSCD II®” and the whole blood collector model “T-RAC II®”, from Terumo BCT®.

For the leukoreduction of the red cell concentrate after being processed with the SABPS, the “Imugard III-RC®” filter from Terumo BCT® was used.

40 WBB model “Reveos LR-EXT” from Terumo BCT® were processed with the ABPS. The device used was the Reveos Automatic Processing System® from Terumo BCT®.

Leukocyte count analysis of the final blood products of SABPS and ABPS was performed with the BD-Leucocount Human Reagent kit on the BD-FACSLytic™ flow cytometer from BD Biosciences®.

The 80 WBB processed with both systems came from normal daily collections and were randomly matched by gender, having 20 from male donors and 20 from female donors for each system.

In both processing methods, three final blood products were obtained: red cell concentrate, platelet concentrate and plasma unit.

A total of 16 parameters were analyzed to obtain the average, standard deviation and p-value between both systems. A comparative table (Table 1) was prepared to present the different parameters and results.

For leukocyte, red blood cell and platelet counts, an additional parameter was included using a mathematical formula to express the total amount in the unit.

## Results

No statistically significant differences (p-value >0.05) were found between the WBB before being processed with SABPS vs. ABPS in any of the parameters analyzed: whole blood volume, hemoglobin, hematocrit, and leukocyte count.

In **red cell concentrates** processed with SABPS vs. ABPS, statistically significant differences (p-value <0.001) were found in red blood cell concentrate volume (SABPS: 232.39 ±19.29ml vs. ABPS: 291.85 ±28.40ml) and hemoglobin amount (SABPS: 18.33 ±0.92gr/dL vs. ABPS: 19.12 ±1.10gr/dL).

No statistically significant differences (p-value >0.05) were found in hematocrit percentage (SABPS: 56.57 ±2.70% vs. ABPS: 57.67 ±3.04%), in leukocyte count (SABPS: 0.286 ±0.249 vs. ABPS: 0.188 ±0.197), nor in platelet count (SABPS: 4.51E+03 ±4.35E+03 vs. ABPS: 1.64E+04 ±5.46E+04).

		Semiautomated System		Automated System		
Product	Parameters	Average	Standard Deviation	Average	Standard Deviation	p-value
Whole Blood Bag	Volume (mL)	445.65	4.14	444.98	3.17	0.415
	Hemoglobin (gr/dL)	12.95	1.17	13.14	1.58	0.548
	Hematocrit (%)	38.46	3.37	38.74	4.49	0.755
	Leucocyte count	5.75E+03	1.16E+03	5.78E+03	1.52E+03	0.916
	Leucocyte count/Unit*	2.56E+09	5.11E+08	2.57E+09	6.78E+08	0.932
Red cell concentrate	Volume (mL)	232.39	19.29	291.85	28.40	0.000
	Hemoglobin (gr/dL)	18.33	0.92	19.12	1.10	0.001
	Hematocrit (%)	56.57	2.70	57.67	3.04	0.093
	Leucocyte count	0.286	0.249	0.188	0.197	0.169
	Leucocyte count/Unit*	3.69E+04	6.00E+04	2.74E+04	4.92E+04	0.441
	Platelet count	4.51E+03	4.35E+03	1.64E+04	5.46E+04	0.174
	Platelet count/Unit**	1.05E+09	1.02E+09	4.95E+09	1.69E+10	0.149
Platelet concentrate	Volume (mL)	59.00	5.64	63.16	4.36	0.000
	Platelet count	1.17E+06	3.62E+05	1.42E+06	4.32E+05	0.005
	Platelet count/Unit**	6.85E+10	2.08E+10	8.97E+10	2.65E+10	0.000
	Leucocyte count	158.28	502.44	497.50	307.78	0.000
	Leucocyte count/Unit*	9.81E+06	3.18E+07	3.30E+07	1.78E+07	0.000
	Red cell count	0.019	0.018	0.033	0.015	0.000
	Red cell count/Unit***	1.10E+09	1.11E+09	2.05E+09	9.78E+08	0.000
Plasma unit	Volume (mL)	203.52	17.85	211.65	29.05	0.136
	Leucocyte count	0.015	0.007	0.006	0.006	0.000
	Leucocyte count/Unit*	3.06E+06	1.44E+06	1.28E+06	1.25E+06	0.000
	Red cell count	0.0030	0.0029	0.0018	0.0013	0.019
	Red cell count/Unit***	6.01E+08	5.70E+08	3.73E+08	2.70E+08	0.025

\*Leucocyte count/Unit = Leucocyte count x Volume x 10<sup>3</sup>

\*\*Platelet count/Unit = Platelet count x Volume x 10<sup>3</sup>

\*\*\*Red cell count/Unit = Red cell count x Volume x 10<sup>9</sup>

**Table 1.** Average and standard deviation of all analyzed parameters from whole blood bags and final blood products processed with the Semiautomated and Automated systems. The statistical significance of each parameter between the two processing systems is expressed as a p-value. Less than 0.05 (<0.05) is considered statistically significant.

In **platelet concentrates** processed with SABPS vs. ABPS, statistically significant differences were found in all the parameters analyzed, being the p-value <0.001 in platelet concentrate volume (SABPS: 59.00 ±5.64ml vs. ABPS: 63.16 ±4. 36ml), in leukocyte count (SABPS: 158.28 ±502.44 vs. ABPS: 497.50 ±307.78) and in red blood cell count (SABPS: 0.0186 ±0.0185 vs. ABPS: 0.0325 ±0.0152); and with the p-value =0.005 in platelet count (SABPS: 1.17E+06 ±3.62E+05 vs. ABPS: 1.42E+06 ±4.32E+05).

In **plasma units** processed with SABPS vs. ABPS, statistically significant differences (p-value <0.001) were found in leukocyte count (SABPS: 0.0150 ±0.0068 vs. ABPS: 0.0060 ±0.0056) and red blood cell count (p-value =0.019) (SABPS: 0.0030 ±0.0029 vs. ABPS: 0.0018 ±0.0013). No statistically significant differences (p-value =0.136) were found in plasma unit volume (SABPS: 203.52 ±17.85ml vs. ABPS: 211.65 ±29.05ml).

## Conclusions

In Hospital Pablo Tobón Uribe Blood Bank Center (Medellín, Colombia) 80 WBB were processed using randomly the SABPS and the ABPS.

Since no statistically significant differences were found in the quality parameters (volume, hemoglobin, hematocrit, leukocyte count) analyzed in the WBB from both compared groups (40 WBB for SABPS and 40 WBB for ABPS), the differences found in the final blood products are based solely on the type of system used.

The statistically significant differences in the quality parameters of the final blood products allow us to objectify a better quality of blood processed with the ABPS compared to the SABPS in terms of total volume and hemoglobin quantity in the red cell concentrate; total volume and platelet count in the platelet concentrate; and lower leukocyte and red cell counts in the plasma units.

Although the leukocyte count in the platelet concentrates obtained by ABPS was higher compared to SABPS, both are aligned and meet transfusion safety standards.

## Bibliography

[1] Glegg, S. M. N., Ryce, A., & Brownlee, K. (2019). A visual management tool for program planning, project management and evaluation in paediatric health care. Evaluation and Program Planning, 72, 16–23. <https://doi.org/10.1016/j.evalprogplan.2018.09.005> [2] Dendere, R., Janda, M., & Sullivan, C. (2021). Are we doing it right? We need to evaluate the current approaches for implementation of digital health systems. Australian Health Review, 45(6), 778. <https://doi.org/10.1071/AH20289> [3] Chaleb, Y. A., Al-Somaiy, A. A., Alamad, M. A., Al Serouri, A. A., & Khader, Y. S. (2019). Evaluation of Blood Transfusion Services in Public and Private Blood Bank Centers, Sana'a Capital, Yemen. Inquiry: a journal of medical care organization, provision and financing, 56, 46958019870943. <https://doi.org/10.1177/0046958019870943> [4] Vermeulen, C., den Besten, G., van den Bos, A. G., Go, M., Gouwerok, E., Vlaar, R., Schipperus, M. R., Spelmink, S. E., Janssen, M., Lagerberg, J. W., de Korte, D., & Klei, T. R. L. (2022). Clinical and in vitro evaluation of red blood cells collected and stored in a non-DEHP plasticized bag system. Vox sanguinis, 117(10), 1163–1170. <https://doi.org/10.1111/vox.13344>