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TYPE OF CELL SEPARATOR, FENWAL AMICUS VS FRESENIUS COM TEC, MAY INFLUENCE THE CORPUSCULAR ELEMENTS VALUE OF THE DONOR`S BLOOD

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SUMMARY

***Introduction**: During the plateletpheresis procedure the number of thrombocytes in the donor's blood significantly decreases, and the levels of the hematocrit (HCT), hemoglobin (Hgb), and leukocyte (WBC) diminish as well. Influence of the cell separator is one of the factors that affects the levels of HCT, Hgb and WBC. In this study, the goal was to determine the value difference of HCT, Hgb, WBC, and platelets after the platelet pheresis process between performance on Fenwal AMICUS and on Fresenius Com Tec.*

***Donors and methods:** The criteria for participation: male in the age range of 25-45. We have formed two groups: for both groups - 180 separations were performed on 60 participants were the values of hematocrits, concentration of hemoglobin and number of leukocytes were established before and after separation using the double-needle continuous flow cell separation (DN-CFCS) on two different devices, Fenwal AMICUS device and the Fresenius Com Tec. device. To confirm the statistical differences we have used Student t-test for independent or dependent samples, as well as Mann-Whitney U test as non-parametric alternative. To compare differences between the values of four parameters (P1-P2) from two groups (using two devices - Fenwal AMICUS and Fresenius Com Tec) The possibility of errors were accepted for $\alpha<0.05$, and the difference between groups as statistical relevant were accepted for $p<0.05$.*

***Results** Statistically significant lower values were noted for all researched parameters after separation on both devices. The statistically significant average values for Hct, Hgb and WBC obtained between two devices, were less than 0.05 ($p=0.05$).*

For the platelets (Plt) there was no statistical significant difference ($p>0.05$ - $\alpha=0.05$), between average level obtained using either Fenwal AMICUS or Frazenius Com Tec.

***Conclusion:** The type of cell separator had the influence on the decrease value of the observed parameters.*

***Key words:** Comparison Fenwal AMICUS and Frazenius Com Tec - plateletpheresis - donor hematological value*

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INTRODUCTION

In transfusion medicine, collecting platelets using apheresis is considered one of the biggest progresses. It permits an adequate response to the fast increasing need for blood components. New technologies have permitted a frequent donation of platelets in contrast to whole blood, while the donors still have joy of helping someone or even saving someone's life.

The purpose of the plateletpheresis procedure is to obtain palatelets concentrate for treating patients in need. During the procedure the number of thrombocytes in the donor's blood significantly decreases, and the levels of the other components of blood as Hct, Hgb and WBC diminish as well.

The undeniable fact is that the platelet count after the separation drastically drops because the procedure was performed to extract a certain amount of them. However, the values of other parameters such as hematocrit, hemoglobin, and leukocytes are reduced in varying percentages, as stated by numerous authors (Benjamin 1999, Bueno 2005, Edwin 2004, Rajendra 2009, Veihola 2006, Fontana 2004, Fontana 2011, Hans-Gert 2013, Al-Raha 2012) health is protected in a way that we have never processed more than one total blood volume (TBV) per procedure, and we have made a sufficient time interval between procedures.

Our goal was to determine the value difference of HCT, Hgb, WBC, and platelets after the plateletphresis between performance on Fenwal AMICUS and on Fresenius Com Tec. cell separator.

DONORS AND METHODS

The results of platelet cytapheresis obtained at the Institute of Transfusion Medicine of F B&H, Sarajevo, Bosnia and Hercegovina, were used in this study.

As sample were used all those donors on the list of the Institute of Transfusion Medicine that had been at least three times blood donors and that had accepted to

participate in this procedure. Out of the register of blood donors of the Institute of Transfusion Medicine using the method of random selection-lottery, the blood donors were chosen to be platelet donors, depending on the needed certain blood groups, the ability to reach the facility in adequate time, the resident distance from the Institute, the time range of previous donations, the current state of health, etc. It fact, we have used this random selection for the samples of respondents from list of donors that all previously agreed to be platelets donors as well.

Recommendations of the Europe Council were fulfilled as well as the domestic legislation. Before the procedure started, the details of the method and the eventual negative side effects during the procedure were explained to the donors. All the donors that participated in the platelet cytapheresis procedure gave their written consent that the obtained results can be used in a scientific research and published with the protection of the donor's identity.

The criteria for participation in the study were as follows: fulfill standard transfusiologic criteria, males between age of 25-45; male donors which have had several platelet apheresis using DN procedures on Fenwal AMICUS device and Fresenius Com Tec. device, using the first three separations and donor's samples with a number of platelet prior procedure above $150x10^9$/L and less than $450x10^9$/L; with expected number of platelets – Yield $\geq 2x10^{11}$/L, with procedure not stopped or shortened. The measured parameters values had to be: for hematocrits> 0.40%, hemoglobin ≥12.5 g/dL; leukocytes 4-10 K/μL. After the procedure were measured: the total amount of processed blood, the separation duration, and the amount of anticoagulant used the volume and the number of obtained platelets.

Criteria for exclusion of the study: donors for which the procedure was stopped or shortened. According to the established goals and conditions for entering the study as well as excluding from the study, two research groups were formed.

Group I – was formed of 60 participants that had 180 separation were the and which values of hematocrit and hemoglobin concentration as well as the number of leukocytes were determined before and after separation performed using DN-CFCS method on the Fenwal AMICUS device.

Group II was formed of 60 participants that had 180 separation were values of hematocrit and hemoglobin concentration as well as the number of leukocytes were determined before and after separation performed using DN-CFCS method on the Fresenius Com Tec.

Our donors were males under 45 years, with body height (TV) between 1.68-2.06 m and the arithmetic mean of 1.82 m while the standard deviation (STDev) was 0.07. The body mass (TM) of the donors varied between 61-168 kg with a arithmetic mean of 93.2 kg while the STDev was 15.50. From these data, the total volume of donor blood (TBV) ranges from 4,370.27 ml to 9,219.39 ml with arithmetic mean of 5,811.89 ml and STDev of 698.36. The number of donors that fulfilled all study conditions was 60 and they were included into the study as participants.

For the study the following equipment were used: cell separator – Fenwal AMICUS, sets for single use Fenwal AMICUS KIT R4R 2314 and Fresenius Com Tec. C5L, anticoagulants ACD.

Methodology of sample taking and analyzing

Parameters that could be changed but are given as defaults before procedure, were: extra volume of physiological solution that was returned to the donor at the end of the procedure in the amount of 60 mL; maximum blood flow was 70 mL/min, limit of the input pressure of -250 mmHg, limit of the return pressure of – 450 mmHg, pressure on the donors arm above the venepunction at the manometer of 50 mmHg, citrate rate of 1.25mg/kg and ACD ratio of 1:10.

The values of platelets, hematocrits, hemoglobin and leukocytes of the donor, before and after procedure, were determined using Electronic counter Cell Dyne 3200 (Abbot Laboratories, IL, USA). Samples for these parameters were taken with eprouvettes (vacutainer with EDTA 5.4 mg/ 3 ml blood) from the vein that will not be used during the procedure. The blood sample after procedure was taken from the entering vein after the end of the procedure and after we have already taken $5ccm^3$ blood in the eprouvette.

Statistical analysis

The data obtained (HCT, WBC, PLT, Hgb) were statistically processed in the following way: The continuous variables which distributions did not have a deviation from the normal were presented as arithmetic average and standard deviation, while as average value and measure of dispersion for continuous variable which distribution significantly differed from normal were presented as the median and interquartile distribution. To confirm the statistical difference we used Student t-test for independent or dependent samples. The possibility of errors were accepted for $\alpha<0.05$, and the difference between groups were accepted as statistical relevant for $p<0.05$. P values that could not be showed with a three decimals digits, are shown as $p<0.001$. The results obtained this way are presented for two groups: A results before procedure (P1) and results after procedure (P2) and B presents compared results between procedures (Fenwal AMICUS: Fresenius Com Tec). For the statistical analysis of the obtained results was used program SPSS for Windows (13.0, SPSS Inc., Chicago, Illinois, and SAD) and Microsoft Excel (Office 2007, Microsoft Corporation, Redmond, WA, and SAD)

Table 1. Differences of observed values before (P1) and after (P2) separation

AparProc		AVG	SD	t	p
AMICUS	P1HCT	45.38	2.69	10.897	<0.0005
	P2HCT	43.69	2.58		
	P1Hgb	15.44	1.00	13.225	<0.0005
	P2Hgb	14.57	1.12		
	P1WBC	7.50	1.98	15.949	<0.0005
	P2WBC	5.92	1.54		
	P1PLT	282.27	54.60	33.485	<0.0005
	P2PLT	202.83	43.04		
FRESENIUS Com Tec	P1HCT	45.03	2.75	8.3610	<0.0005
	P2HCT	43.88	2.79		
	P1Hgb	15.46	1.00	12.604	<0.0005
	P2Hgb	14.89	0.99		
	P1WBC	7.84	1.99	18.422	<0.0005
	P2WBC	6.34	1.67		
	P1PLT	279.56	52.27	36.958	<0.0005
	P2PLT	200.01	39.83		

t-test for dependent samples

Table 2. Differences for the observed values between AMICUS and Fresenius Com Tec

	AparProc		t-test	p
	AMICUS	Fresenius ComTec		
P1HCT; χ^2±SD	45.37±2.68	45.03±2.74	1.21	0.229
P1Hgb; χ^2±SD	15.44±1.00	15.45±.0.99	-0.14	0.889
P1WBC; χ^2±SD	7.49±1.97	7.84±1.99	-1.64	0.101
P1PLT; χ^2±SD	282.27±54.60	279.56±52.27	0.48	0.631
P2HCT; χ^2±SD	43.68±2.57	43.88 ±2.79	-0.67	0.504
P2Hgb; χ^2±SD	14.57±1.12	14.89±0.99	-2.83	0.005
P2WBC; χ^2±SD	5.92±1.54	6.34±1.67	-2.48	0.014
P2PLT; χ^2±SD	202.83±43.04	200.01±39.83	0.65	0.519

Student t-test; χ^2±SD = Arthmetic mean and standard deviation

RESULTS

The values of hematocrit (HCT), leukocytes (WBC), platelets (PLT) and hemoglobin (Hgb) were presented before (P1) and after separation (P2), as well as the difference of these values and the comparison of the results between the two cell separators. At the initial values, before separation (P1), the parameters (HCT, Hgb, WBC and PLT) had no statistical differences between Group I and Group II (Table 1).

Statistically significant lower values were observed of all researched parameters after donor's sample separation performed on the Amicus device and donor's sample separation performed on the Fresenius Com Tec **(**Group I and Group II.**)**

We found that the significance level, for the variable: hemoglobin Hgb and leukocytes WBC were less than 0.05 (p=0.05), there was a statistical significant difference between the average values for the DN procedure performed on the Fenwal AMICUS device and Frazenius Com Tec.device (Table 2).

For the variable platelets (PLT) there was no statistical significant difference of average level (significance level is more than 0.05 - α=0.05), between performance of either the Fenwal AMICUS device or Frazenius Com Tec. device.

DISCUSION

The conclusion that can be drawn from this statistical analysis is that: the both groups had the statistical significant decrease in the value of hematocrit, in the concentration of hemoglobin and in the number of leukocytes and platelets after procedure was completed.

One can conclude that the decrease of the values of the measured parameters after procedure completing can be related to the parameters values that donor had before the procedure. Other authors have obtained similar results that can confirm our results (Hans-Gert 2013, Al-Raha 2012, Altuntasa 2008, Das 2009, Bereta 1998, Chaudhary 2009, Vamvakas 2009).

The comparison of the results between Group I and II for hematocrit, concentration of hemoglobin and number of leukocytes after platetelpheresis performed by the DN-CFCS method on Fenwal AMICUS device and FRESENIUS ComTec. device allow us to conclude with following facts: Comparing the parameters of leukocytes and hemoglobin's, we found a statistical significant difference in the decrease of the parameter's value after separation, there was a significant decrease change in using Fenwal AMICUS cell separator compared to using FRESENIUS cell separator with the same procedure. The same conclusion got O˙Meara et al. 2012.

For the platelets amount values we have found that there are no significant statistical differences. Many authors confirmed the same results when compared cell separators (Fontana 2011, Hans-Gert 2013, Bereta 1998, Chaudhary 2009, Vamvakas 2009, Tendulkar 2009, Patidar 2013, Rosencher 2011).

Regardless of the cell separator, the decrease in the values of hematocrits, the concentration of hemoglobin, the number of leukocytes or the platelets were such that they would endanger the donor health nor the values after procedures were decreased under the lower physiological level.

Das et al. 2009 mentioned that in a certain number of donors there was a decrease, most commonly of hemoglobin or platelets, under the level considered physiological with no clinical manifestations, while some others mentioned severe clinical manifestations (Rosencher et al. 2010). Neither of that was the case in our study.

CONCLUSION

Based on the analyzed data collected during this study we came to several conclusions. A good selection of the donors is the primary precondition for a good but also a safe platelet separation for the donor. In all observed platelet separations, regardless of the cell separator used, there was a decrease of hematocrits values, concentration of hemoglobin, number of leukocytes and platelets of the donor after platetcitopheresis.

The choice of cell separator had influence on the observed parameters decrease. The cell separator Fresenius ComTec was more "sparing" for the donors when observing the results of leukocytes and hemoglobin after separation while for the platelets and the hematocrits difference was not observed. If the procedure is performed according to the given instructions and recommendations, and if the cell separators are well taken care of according to the manufacturer recommendations than the health risk for the donor is minimized and there are no clinical consequences side effects.

Plateletcytopheresis will in the future become the main source for platelets concentrations for treating the most serious illness. Platelet concentrations obtained by platelet cytopheresis is the best way to overcome the gap between the need of "rare" blood groups and the possibilities that transfusion departments can offer.

Regardless of technological progress, the control of hematocrits, hemoglobin, leukocytes and platelets of the blood donor must be performed prior separation. In practice, new technologies are accepted and only viewed from their positive effects not taking into account collateral effects, that although not dramatical, can after a while have a cumulative effects and one must take care about it.

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Declaration of Ethical Committee: By the Decision of Ethical Committee number 03-1703-14.212.1/14 of 26th of March 2014, the research components were approved and valorized.

Informative consent of each participant of this study was signed.

Conflict of interest : None to declare.

Contribution of individual authors:

Elvedin Landzo: conception and design of the publication, literature searches and analyses, acquisition of data, interpretation of results, writing the first draft participate in drafting the article, executionof tables, approval of the final version;

Izeta Aganovic-Musinovic: statistical analyses, participate in revising it critically for important intellectual content, approval of the final version;

Danijel Bevanda: participate in revising it critically for important intellectual content, approval of the final version;

Ante Bogut: participate in revising it critically for important intellectual content, approval of the final version.

Ivan Vasilj: participate in revising it critically for important intellectual content, approval of the final version;

Daniela Bevanda Glibo: revising the manuscript, approval of the final version;

Ivana Bjelanovic: revising the manuscript, approval of the final version.

References

1. *Benjamin, RJ, Rojas P, Christmas S, Neal J, Broughton S, et al.: Plateletpheresis efficiency: a comparison of the Spectra LRS and AMICUS separators. Transfusion 1999; 39:899*
2. *Bueno JL, García F, Castro E, Barea L, González R: A randomized crossover trial comparing three plateletpheresis machines. Transfusion 2005; 45:1373*
3. *Edwin A, Burgstaler EA, Jeffrey L, Winters A. et al.: Paired comparison of Gambro TrimaAccel versus Baxter Amicus single-needle plateletpheresis. Transfusion 2004; 44:1620*

4. *Rajendra Ch, Das SS, Dheeraj K, Shashank O, Sunil V: Donor safety issues in high-dose platelet collection using the latest apheresis systems. The Authors. Journal compilation 2009 LMS Group Ltd*
5. *Veihola M, Aroviita P, Linna M, Sintonen H, Kekomaki R: Variation of platelet production and discard rates in 17 blood centers representing 10 European countries from 2000 to 2002. Transfusion 2006; 46:991-5*
6. *Fontana S, Keller P, Taleghani BM: Prospective, paired crossover comparison of multiple, single-needle plateletpheresis procedures with the Amicus and TrimaAccel cell separators. Transfusion 2006; 46:2004-10*
7. *Fontana S, Keller P, Taleghani MB: Platelet Recruitment during Multiple Donor Platelet Apheresis Differs between Cell Separators' Transfus. Med Hemother 2011; 38:195–198*
8. *Hans-Gert HG, HeuftRainer R, MoogEike G, Fischer EG, Jürgen J, Zingsem A: Donor safety in triple plateletpheresis: results from the German and Austrian Plateletpheresis Study Group. multicenter trial 2013; 53:211-220*
9. *Al-Raha K: Plateletpheresis concentrate produced with Fresenius cell separator Iraqi experience. Mustansiriya Medical Journal 2012; 11*
10. *Altuntasa F, Sarib I, Kocyigita I, Hacioglub SA, et al.: Comparison of Plateletpheresis on the Fenwal Amicus and Fresenius Com.Tec Cell Separators. Transfus Med Hemother 2008; 35*
11. *Das SS, Chaudhary R, Verma S K.,Ojha S, Khetan D. Pre- and post- donation haematological values in healthy donors undergoing plateletpheresis with five different systems. Blood Transfus 2009; 7:188–192*
12. *Bereta F, van den Bosch S, Castelli D, Cavalli F, Ghielmini M: Intrapatient comparison of an intermiTMent and a continuous flow cell separator for the collection of progenitor and stem cells from the blood. Vox Sang 1998; 75:149-153*
13. *Chaudhary R, Das SS, Khetan D, Ojha S, Verma S: Comparative study of automated platelet pheresis using 5 different apheresis system in a tertiary care hospitals. Transfus Apher Sci 2009; 40:99-103*
14. *Vamvakas EC: Relative safety of pooled whole blood-derived VS. Single–donor (apheresis) platelet, in USA a systemic review of disparate risks. Transfusion 2009; 49:2743-58*
15. *Tendulkar A, Rajadhyaksha SB: Comparison of plateletpheresis on three continuous flow cell separators. Asian J Transfus Sci 2009; 3:73-77*
16. *Patidar GK, Sharma RR, Marwaha N. Frequency of adverse events in plateletpheresis donors in regional transfusion centre in North India. Transfus Apher Sci 2013; 49:244-8*
17. *O'Meara A, Infant,i L, Sigle J, Stern M, Buser A: Switching iron-deficient whole blood donors to plateletpheresis. Transfusion (2012; 52:2183-2188*
18. *Rosencher J, Zuily S, Varenne O, Spaulding C, Weber S: Acute myocardial infarction secondary to platelet apheresis in a 57-year healthy donor. Int J Cardiol 2011; 150*

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