Initial Values of Donor Hematocrit and Efficiency of Plateletpheresis

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1. INTRODUCTION
The development of medicine, or the new and aggressive diagnostic and therapeutic methods and procedures, especially in the field of oncology and hemato-oncology lead to increasingly severe and protracted thrombocytopenia (1, 2). Medicine requirement is that, in the case of platelets, from each separation, or donor, obtains the dose with as large as possible platelet count, but also a higher quality product in less time. Studying the factors that affect the results of apheresis is one of the directions to satisfy the needs for platelets concentrates. An important parameter is the calculation of the efficiency of platelet collection.

On the efficiency of collection of platelets by cell separator could influence a number of factors: the initial value of the donor platelets, hematocrit, etc. For the process of selection of donors Council of Europe has adopted several recommendations that have been promoted in Article 2 Council of Europe Recommendations No. R (95) (3, 4, 5). Platelet concentrates for transfusion can be obtained in several manners:

- From donations of whole blood with anticoagulant;
- Platelet rich plasma (PRP);
- By buffy coat method;
- By apheresis on different types of machines.

The term is used to make distinction between platelets obtained from apheresis that are designated as specific donor platelet concentrate. Collection of platelets by apheresis is considered one of the greatest advances in transfusion medicine. It provides an adequate response to rapidly growing demand for blood components. New technology has enabled more often donating platelets than whole blood, reducing the number of leukocytes without filtration. Administration of these platelets significantly reduced the risk of alloimmunization. Exact name of this procedure is platelet pheresis, but is better known as single donor platelets apheresis. This procedure has a higher content of platelets (absolute number, yield and potency) that is present in a dose of platelets than the one obtained from the individual dose. Approximately, 5-11 individual doses, obtained from whole blood equal the dose obtained by apheresis. During method called citrated apheresis donor blood passes through the cell separator, where the blood is separated by centrifugation.
on the basis of specific gravity in multiple layers such as layer of red blood cells, white blood cells, platelets and plasma. Certain procedures involve two venipunctures and continuous flow and the other one venipuncture with alternating return and extraction of blood from a vein. Most of today’s devices can use both methods depending on which program the separator is set and they are labeled as SN (single needle) or DN (double needle) (1, 2, 3, 4, 5). The higher yield (total number of collected platelets) is reached if the donor has a higher initial platelet count, and the separation duration is shorter. One of the parameters is also the efficiency of the aggregation of platelets (expressed in percentages) which values may have direct or indirect influence. Hematocrit (Hct) is the percentage of blood that makes cellular elements. Initial hematocrit of donors is very important parameter for platelets apheresis and not only as a parameter that speaks about the health of the donor, but also as a value that, by the way that is reached, has much in common with the essence of the apheresis procedure, and that is centrifuge.

2. GOALS

Calculate the efficiency of the platelets aggregation in the cell separator Baxter Fenwal AMICUS s.n.2.51.

To compare the efficiency of the aggregation of platelets with hematocrit values.

3. DONORS AND METHODS

During the donor selection process we followed the recommendations of the Council of Europe, which are recommended and promoted in Bosnia and Herzegovina. Besides general, the criteria for inclusion in the study were:

- Donors men and women with the values of platelets before the procedure of 200-450 x 10^9/L
- Estimated Yield ≥ 4 x 10^11
- The blood flow greater than 55 ml/min and less than 70 ml/min
- The process was not interrupted or shortened
- That after the procedures are measured values of the donor platelets;

- That after the procedures are measured values of platelets in the product and yield is calculated. The procedures were performed with the following appliances and equipment:
  - Fenwal Baxter AMICUS REF 4R4580.
  - Disposable sets with code R4R2314 (4, 5).
- Values of platelet count. Hct, hemoglobin and white blood of donors, before and after the procedure, were obtained using appliance BD QBC Autoread with the prior centrifugation of the sample in BD QBC Centrifuge.

The samples for these parameters are taken into tubes (Vacutainer with EDTA 3.4mg 3ml of blood) before the procedure from a vein that will not be used during the procedure. The blood sample is taken after the procedure from the input veins after the procedure is completed and after we took 5 cm^3 of blood in a test tube, from which we will not make these measurements. Measurement of platelet counts were done on the AVL Cellcounter Autolyser AL 816 after we took a sample of the product 6-24 hours after processing, in the appropriate container. The total number of collected platelet count is the function of product volume and concentration of cells in the product. Calculation of anticipated collection efficiency is obtained by dividing the total number of cells collected from the predicted total number of cells that are processed, or passed through the machine. The estimated number of processed cells is calculated when the average number of platelets (which we obtain from the total number of donor platelets before and after pheresis is divided by two) multiplied by the volume of blood processed reduced by ACD quantity. Using the following mathematical operation we are computing the number of platelets in the final product: The platelet count in the product (Yield) = volume of product (mL) x platelet count (platelets/ul) x conversion factor (10000/ul/mL).

Using the following mathematical operation we calculate the efficiency of collection-collection efficiency: total platelet count = [(before + after the number (platelets/ul)) / 2] x volume of processed blood (mL) x conversion factor 10000 ul / mL). Based on the initial values of hematocrit values all samples are divided into groups-C (baseline Hct was=46) and D (baseline Hct=46). In data analysis and graphical presentation we used the software SigmaStat 3.5.Ink and Microsoft Office XP Professional Excel or Equal Variance Test, Mann-Whitney Rank-Sum Test.

4. RESULTS

At the AMICUS separator was made 258 separations that met the requirements for entry into the study. From 258 separations there were 226 (87.6%) male donors and 32 (12.4%) women donors which indicate that women who have decided to become platelets donors are less often than men.

Comparing the same groups in relation to baseline hematocrit (Hct), it can be noted that women have lower Hct and higher SD. There was a statistically significant difference and the value is higher in men than women donors (table 1.1).

| Separations | N  | Min | Max | Avg | SD |
|-------------|------------------|------------------|------------------|------------------|------------------|
| M           | 226  | 40  | 52.4 | 46.99 | 2.57 |
| F           | 32   | 38.8| 50.7 | 44.26 | 3.00 |

P = 0.289; Equal Variance Test: P = 0.696

Table 1. Hct of donors before separations and according to gender

There was a statistically significant difference in Hct values between groups and it was higher in group D than in group C. The average value of Hct of donors before the separation was 46.66. The range of minimum and maximum values was from 38.8 to 52.4±2.78. The difference in Hct values between the genders exist and Hct was significantly higher in men than in women. Hct value average for men was 46.99±2.78 and for women 44.26±3.00. In relation to the relevant data of other authors, our donor Hct values were higher. It is interesting that the values of Hct among women
in our material are higher than Hct value of all donors in the studies of other authors (15, 16, 17, 20). (table 2.)

There was a statistically significant difference in the baseline platelet count of donors in groups C and D, while platelet counts were significantly higher in group D. (table 3.)

Table 3. Initial value of platelets in groups C and D.

|     | N  | Min | Max | Avg. | SD  | SEM |
|-----|----|-----|-----|------|-----|-----|
| C   | 104| 47.45| 85.22| 68.34| 6.91| 0.678|
| D   | 154| 36.65| 84.45| 61.31| 7.30| 0.588|

P = 0.420; Equal Variance Test P = 0.881

There was a statistically significant difference in the efficiency of separation between groups C and D and the efficacy was lower in group D. (table 4.)

Table 4. Efficiency in groups C and D.

|     | N  | Min | Max | Avg. | SD  | SEM |
|-----|----|-----|-----|------|-----|-----|
| C   | 104| 45    | 85 | 68.34| 6.91| 0.678|
| D   | 154| 45    | 85 | 61.31| 7.30| 0.588|

P = 0.420; Equal Variance Test P = 0.881

There was a statistically significant negative correlation between the correlated variables separation efficiency and variable initial values of Hct, or while the value of variable Hct increases, the value of variable efficiency decreases. (figure 1.)

Correlation coefficient r = -0.526; N = 258.

5. DISCUSSION

By random sampling by groups C (baseline Hct ≤46) and D (baseline Hct>46) based on the values of Hct, we get groups with 104 and 154 samples respectively. Hct values in groups by gender were processed in our results. We found that in group C there was 25 (78.13% of all separations in which women are donors) women, and in group D, with larger values of Hct, only 7 (or 21.87%).

Initial value of Hct in group C was 43.94±1.66 with a range between minimum and maximum values from 38.8 to 46 in group D, this value was 48.49±1.65 with a minimum 46.1 and maximum of 52.4. There was statistically significant difference. This result was expected, given that the randomization was done on the basis of initial Hct values.

The efficiency of the aggregation of platelets in groups C and D was significantly different and higher in group C than in group D. The value in group C was 68.34±6.91 and in group D 61.31±7.30. Correlation of variables efficacy and Hct was significant (r =-0.526) and as the higher value of Hct is the less is efficiency of collecting platelets. These results, although not the basis of our work, are somewhat unexpected, although we cannot say that they are surprising. Some authors mention such a possibility, though by the correlation between efficacy and hemoglobin values, but could not find the relevant study of other authors that explicitly deals with this problem. Given that in our study was analyzed a representative sample of 258 members, it gives us the right to say that the efficiency of separation of platelets by Hct is significantly affected (18, 19, 20).

By analyzing baseline platelet count in groups C and D, we found a statistically significant difference. The initial value of the number of platelets in group D were higher (297.50±52.71) than in group C (281.65±57.67), but the differences have no significant practical importance to the efficiency of the aggregation of platelets. This difference has implications for the duration of the separation, because baseline platelet count does not affect the separation efficiency but its duration.

6. CONCLUSION

Summarizing the results of analysis in our study we can summarize the following facts:

We cannot be satisfied with the number of women platelets donors, but it is a problem that is related to the condition of blood donations in our country. As the relation of the state and society to this problem is changing, also the situation about donating blood, donating organs and cells in general will change.

Hct value of the donor before separations has no effect on the duration of separation, but the impact of Hct on the efficiency of platelet collection is significant. Specifically, increasing the value of Hct significantly reduces the efficiency of platelet collection (18).

In practice, based on the facts presented, we can make even better selection of donors. In this selection we should prefer donors with higher baseline platelet counts and lower Hct values. In this way, we can collect a higher yield, have lower duration of separation and increase the efficiency of platelet collection. The benefit is for the medical community due to higher values of yield, but also financial due to the shorter duration and higher separation efficiency. Because of the high cost of performing this procedure financial effect is very significant.

Rapid development of transfusion technology gives great importance to the use of apheresis machines that enable the collection of all blood components. In this case the standard product obtained by apheresis is likely to become in the future the only desirable, or their meaning and usage will grow steadily in accordance with the increased need for platelets.

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