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The Safe and Effective Plateletpheresis

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Abstract

At the Research and Production Center of Transfusion platelet production have mainly supported (about 99%) by apheresis. However, apheresis donations have limitations caused by donor fitness due to both their preferences and their platelet pre-count validity. So, it is important to maintain of single donor high-dose plateletpheresis by improving its efficacy and safety. The aim of study was to develop of safe-effective approaches of plateletpheresis. Donors had been attracted to the study if they had filed of informed consent for post-collection blood sampling in advance. They were selected with following criteria: male, age 18-60 years, weight ≥ 55 kg, Hb ≥ 125.0 g/L, PLTs ≥ 160.0 × 10^9/L. Target number of platelets need to be obtained was chosen under calculation of estimated donor post-collection platelets. Platelets were harvested by «Hemonetics MCS plus» separators with LDP protocol, blood samples were counted by «Sysmex» hematology analyzer. Thus, 16 apheresis procedures with volunteer-donors were studied. The following results are demonstrated in the present study: donor pre-collection platelets 286.0 × 10^9/L ± 27.2; donor blood volume calculated by separator 5481.6 mL ± 408.5; platelet yield 473.1 × 10^9/unit ± 47.7; donor blood processed 3190.8 mL ± 189.7; donor platelets processed 763.0 × 10^9 ± 55.6; actual donor post-collection platelets measured by lab 193.3 × 10^9/L ± 18.6; platelet collection efficacy 61.9% ± 3.0. The values of estimated post-collection platelets 199.0 × 10^9/L ± 21.3 were not significantly different from those with actual post-collection platelets 193.3 × 10^9/L ± 18.6 (χ^2=0.401). Thus, plateletpheresis efficacy has to be controlled using calculation of estimated donor post-collection platelets by making sure that safe threshold of post-apheresis platelet number is provided. The further studies have to be proceeding due to small number of observations.

Keywords: High-dose plateletpheresis; Platelet collection efficiency; Target number of platelets

Introduction

Apheresis is a donation procedure with drawing of blood extracorporeal to separate it into its components with following collection of desired components and returning of remaining ones to the donor. Currently, new apheresis machines are able to collect any blood components and wherein the blood is processed in a small extracorporeal volume [1-3]. Apheresis technologies support the best management of blood supply due to substantial improving of productivity and quality of component collection [4-8]. Thus, in a recent past it was expected that the blood donation settings in their prospective strategy most likely to be shifted toward the apheresis including of platelet production [4]. However, the present experience of European countries shows apheresis platelet preparation indices observed between their Blood Services are various with scattering in a large range from 10% to 98% [9-11]. At the Research and Production Center of Transfusion, Astana, Kazakhstan, platelet production have mainly supported (about 99%) by apheresis collection according to the annual reporting from last 3 years. However, apheresis donations have some limitations caused by donor fitness due to both their preferences and their platelet pre-count validity that in turn may sustain of donor deficiency. Therefore, it is important to maintain of single donor high-dose plateletpheresis by improving its efficacy and safety [12]. Moreover, such approach with high-dose plateletpheresis is clinical beneficial too, since it helps to avoid of platelet over-transfusion in the patients with thrombocytopenia and consequently decreases the adverse effects of transfusion and by doing so it will protect the patients from an exceeding donor exposure [13-20]. Usually, the plateletpheresis procedures lead to serious adverse reactions very rarely [21,22]. Nevertheless, a high-dose plateletpheresis may cause to some decreasing of donor hematology parameters despite of their normal patterns before procedure [12,23-25]. It is very sensitive especially in donors with low normal platelet pre-count (150.0-200.0 × 10^9/L) and hemoglobin concentration (125.0-130.0 g/L) [23].

According to Kazakh Blood Service standards, one-dose units of apheresis platelets should contain 200.0 × 10^9 platelets as minimum and double-dose units should contain 400.0 × 10^9 cells as minimum, respectively. Meanwhile pre-donation peripheral blood platelets should not be less than 160.0 × 10^9/L to allow a person to be a donor at all. These standards are not sufficient for a plateletpheresis practice because of their inability to explain how many platelets can be collected from a donor and at the same time how many of platelets will be remain in a bloodstream right after procedure. Thereby, determination of target number of platelets by estimation of expected number of post-collection platelets is a turning point to trigger procedure.

Aim

To develop the safe-effective approaches of plateletpheresis.

Materials and Methods

Prospective study of plateletpheresis procedures with 16 standard donors in the period November–December, 2015.

Study location

Research and Production Center of Transfusion, Astana, Kazakhstan.

Equipment

MCS plus Hemonetics blood separator, Sysmex hematology analyzer.

Object of study

A number of donor peripheral platelets before and after plateletpheresis procedure.

Unit of study

A standard examined donor.

Donor selection criteria

Male sex, age 18-60 years old, weight ≥ 55 kg, hemoglobin ≥125.0 g/L, platelet pre-count 160.0 × 10^9/L.

Sampling

Random stratification.

Statistical processing methods of materials

Quantitative content analysis, descriptive statistic, chi-square, comparison and relationship, straight ranking.

Results

The study was conducted in accordance to algorithm drawn up preliminarily (Figure 1).

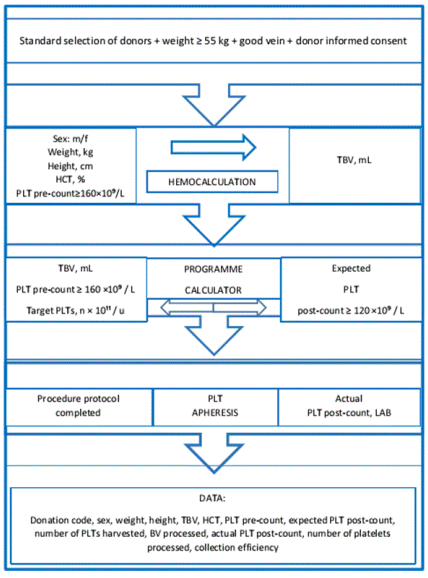

Figure 1: Algorithm of study.

Pre-donation lab testing set included hemoglobin concentration, hematocrit, number of platelets, Lee-White clotting time.

All studied donors were regular and had a routine inter-donation interval, which was at least not less than 2 weeks according to National Blood Service Policy. Donors were attracted to the study if they had filed of informed consent for a post-collection blood sampling in advance. They were selected with following criteria: age 18-60 years, weight ≥ 55 kg, Hb ≥ 125.0 g/L, PLTs ≥ 160.0 × 10^9/L.

Thus, 16 apheresis procedures with volunteer-donors were studied. Platelets were harvested using «Hemonetics MCS plus» separators with LDP protocol. All procedures were performed according to manufacturer's manual and standard operating procedure. Saline compensation was administered during apheresis. No adverse events and reactions were observed.

Additional blood samples were withdrawn to EDTA vacuum vials from intact vein after procedure and they were counted using «Sysmex» hematology analyzer. The main parameter of lab counting was a number of platelets that was necessary to compare it with a number of platelets expected to be leaving in a donor bloodstream after procedure.

Before each procedure the target number of harvesting platelets was determined that in turn was dependent from estimation of donor post-collection platelets calculated by next formula:

$$Plt\ \ post = \frac{(BV \times Plt\ \ pre) - Plt\ \ yield}{BV}$$

Where,

Plt post: Number of donor peripheral blood platelets expected after procedure (platelet post-count estimated), × 10^9/L;

BV: Donor blood volume calculated by separator, L;

Plt pre: Number of donor peripheral blood platelets before procedure (actual platelet pre-count), × 10^9/L;

Plt yield: Number of harvested platelets, × 10^9/u;

So, any desired number of platelets that need to be harvested, otherwise known as a target number of platelets, was chosen and entered to the program of procedure if estimation has not lead to donor platelets decreasing to 120.0 × 10^9/L or less after apheresis. This number was taken into account each time as a safety threshold.

Collection efficiency was calculated by next formulas [24]:

$$Total\ \ Plt\ \ processed = \frac{Plt\ \ pre + Plt\ \ post}{2} \times Total\ \ BV\ \ processed$$

Where,

Total Plt processed: Number of platelets processed during procedure, × 10^9;

Plt pre: Donor peripheral blood platelets before procedure (actual platelet pre-count), × 10^9/L;

Plt post: Number of donor peripheral blood platelets after procedure (platelet post-count estimated), × 10^9/L;

Total BV processed: Donor blood volume processed during procedure, L;

$$Total\ \ Plt\ \ processed = \frac{Plt\ \ pre + Plt\ \ post}{2} \times Total\ \ BV\ \ processed$$

Where,

CE: Efficiency of platelet collection, %;

Plt yield: Number of harvested platelets, × 10^9/u;

Completed apheresis protocols from separators were widened by adding all of information related to donors, procedure statistic and lab testing for further creating of common data of study (Figure 1). Data were processed statistically using Excel program.

Thus, the present study has demonstrated the following results shown in the Table 1. The mean blood volume from separator program calculator was 5 481.6 mL ± 408.5 (Figure 2) including of ACD-A anticoagulant consumption rate, med 5 411.5. The mean pre-donation platelet count was 286.0 × 10^9/L ± 27.2 (Figure 3), med 280.5. There 0.58 of blood volume was processed in average because of 3 190.8 mL ± 189.7 mean blood volume is processed, med 3 164.5 (Figure 2).

Parameters	Values				
	Min	**Max**	**Mean**	**SD**	**Med**
BV, mL	4 767.0	6 312.0	5 481.6	408.5	5 411.5
HCT, %	37	43	42.8	3.2	41
PLT pre-count (lab), × 10^9/L	236	341	286	27.2	280.5
PLTs yield, × 10^9/u	400	580	473.1	47.7	475
BV processed, mL	2 886.0	3 532.0	3 190.8	189.7	3 164.5
PLT post-count estimated, × 10^9/L	162	243	199	21.3	196
PLT post-count actual (lab), × 10^9/L	164	237	193.3	18.6	194.5
PLTs processed, × 10^9	658.53	848.65	763	55.6	776.8
CE, %	58	69	61.9	3	61

Table 1: Donor hematology parameters, plateletpheresis procedure statistic and efficacy of platelet collection (n=16).

All administered procedures were double-dose apheresis with obtaining 473.1 × 10^9 ± 47.7 platelets per unit in average (Figure 4), med 475.0.

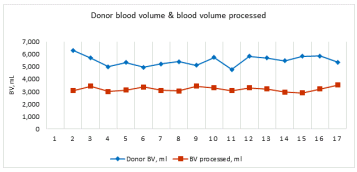

Figure 2: Donor blood volume calculated and blood volume processed (n=16).

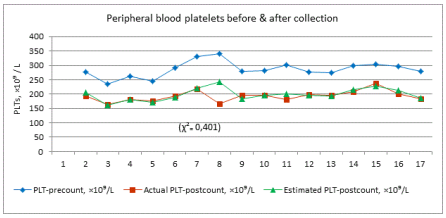

Figure 3: Donor peripheral blood platelets before and after plateletpheresis (n=16).

The rate of post-collection donor peripheral blood platelet dropping was 1.4 times approximately, and excessive decreasing of platelets was not observed either from actual or from estimation. Moreover, the values of actual (lab counted) post-collection platelet number 193.3 × 10^9/L ± 18.6, med 194.5 were not different significantly (χ^2=0.401) from those with platelet number estimated 199.0 × 10^9/L ± 21.3, med 196.0 (Figure 2). The platelet collection efficiency was satisfactory with their average 61.9% ± 3.0, med 61.0% (Figure 4).

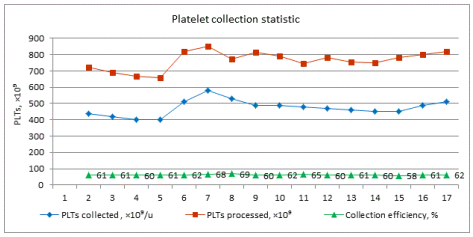

Figure 4: Platelet collection statistic and collection efficiency (n=16).

Conclusion

Our experience with resolving of issues related to platelet collection efficiency shows that estimation of platelet post-count is a crucial instrument to support of donor safety. Using a calculation of post-collection platelet number to setting of target number of platelets helps

to improve the apheresis productivity. The accuracy of this approach has been verified by lab assays of the donor blood samples taken right after apheresis. Thus, plateletpheresis efficacy has to be controlled using calculation of expected (estimated) donor post-collection platelets by making sure that safe threshold of post-apheresis platelet number is provided. The further studies have to be proceeding due to small number of observations.

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