

#### **ORIGINAL ARTICLE**

# Plateletpheresis: A comparison between two blood cell separators at a tertiary care facility.

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**ABSTRACT... Objective:** To evaluate the performance of two different cell separators used for plateletpheresis at our facility. This evaluation was done to ascertain which cell separator performed better in terms of various product parameters. **Study Design:** Cross Sectional study. **Setting:** National Hospital, Lahore. **Period:** July to December 2020. **Material & Methods:** A total of 100 plateletapheresis procedures were done, 50 on Cobe Spectra and 50 on Haemonetics MCS900. Male donors were selected after detailed medical history, screening and informed consent. For each cell separator, the total procedure time, collection rate and platelet yield of the final product (single donor platelets) was noted and compared. The predonation platelet count of each donor was also recorded. **Results:** Donor turnaround time was better for the Cobe 60.1 + 2.757 min vs 81.1 + 3.311 min on Heamonetics (p value < 0.0001). Cobe had a superior collection rate 0.065+0.0088 (PLT×10<sup>11</sup>/ min) than Heamonetics 0.0519 + 0.007 (PLT×10<sup>11</sup>/min) (p value< 0.0001). For both cell separators, the final product was similar in terms of platelet yield (p value = 0.56). Overall, donor predonation platelet counts ranged from 220-480x10<sup>9</sup>/L. Pearson correlation test showed positive correlation (r = 0811, p value; < 0.0001) between platelet yield and donor platelet count. **Conclusion:** Continuous flow cell separators, like the Cobe spectra, offer a high quality platelet product with greater efficiency when compared to intermittent flow cell separators like the Haemonetics.

Key words: Apheresis, Platelet, Thrombocytopenia.

## INTRODUCTION

Platelet concentrate is an invaluable support product in many clinical scenarios.<sup>1</sup> These include patients undergoing chemotherapy, bone marrow failures syndromes, prophylactic transfusions andplatelet dysfunction disorders.<sup>2,3</sup> The merits of single donor plateletsover random unit are numerous. These include reduction in multiple exposures, HLA alloimmnization and potential transmission of viral diseases. Cell separators are instruments employed for plateletaphersis procedures.<sup>4</sup> They operate on the principle of either intermittent flow centrifugation (IFC) or continuous flow centrifugation (CFC). Apheresis technology has evolved over time, the newer instruments ensuring higher yield, efficient collection and better leucodepletion.<sup>5</sup>

In this study, we compared 2 cell separators

used for platelepheresis at a tertiary care facility. The data obtained was used to assess product characteristics and evaluate suitability and convenience with regard to selection of apheresis equipment for future apheresis procedures at our facility.

## **MATERIAL & METHODS**

Following approval from institutional ethical review board (CIP/IRB/1042), we obtained 50 data for plateletpheresis procedures done on the Cobe spectra leukoreduction system, (TerumoBCT) and 50 for the Haemonetics MCS9000.<sup>6</sup> Donors were randomly selected from the donor pool reporting to the blood bank at our facility. Donors were selected as per standard American Association of Blood Banks (AABB) guidelines for plateletpheresis. It was ensured that the following criteria were met:

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Age > 18 yr, weight > 50 kg, hemoglobin > 12.5g/dl, platelet count > 220 x  $10^{9}/L$ , negative for Hepatitis B, C, HIV, and Syphilis.

By using WHO sample calculator:.

$$n = \frac{2\sigma^2 (z_{1-\alpha/2} + z_{1\beta})^2}{(\mu_1 - \mu_2)^2}$$

Sample size of 100 (having 50 in each group) was calculated with level of significance 5%, power of test 90%, test value of population mean<sup>16</sup>  $3.54 \times 10^{11}$  and anticipate population mean<sup>21</sup> of 4.05  $\times 10^{11}$  with population SD 0.552.

Donors who had donated single donor platelets twice in past 7 days or those with intake of NSAIDS or antiplatelet drugs in past 7 days were excluded. Informed consent was taken from selected donors and they were monitored for any signs of hypotension/hypocalcaemia during plateletphereis. For predonation complete blood count, 3ml of anticoagulated peripheral blood (K<sub>2</sub>EDTA) was collected and run on Sysmex hematology analyzer XN 9000, (Sysmex, Kobe, Japan).

Product parameters that were analyzed included the total procedural time (minutes), final product volume (ml), platelet count prior to donation  $(x10^{9}/L)$ , and platelet yield  $(x10^{11})$ .<sup>7</sup>

Platelet Yield=Volume of the product (ml)  $\times$  Product count (platelet/µl)  $\times$  Conversion factor volume (1000 µL/ mL)

All data was evaluated on the Statistical Package for Social Sciences (SPSS) version 20. Mean and standard deviation were calculated for all variables. Independent samples t-test was applied to evaluate differences between both groups. Pearson coefficient was calculated to evaluate relationship between platelet yield and donor platelet count.<sup>8</sup> P- Value less than 0.05 was considered statistically significant.

# RESULTS

The mean donor age was 36.12 + 3.166 for the Heamonetics and 35.5 + 2.383 years for the Cobe Spectra. Other donor parameters are shown in Table-I.

Donor turnaround time was significantly less on the Cobe .i.e. 60.1 + 2.757 min vs 81.1 + 3.311 min on Heamonetics (p value < 0.0001). The collection rate also differed, 0.065+0.0088(PLT×10<sup>11</sup>/min) for Cobe and 0.0519 + 0.007(PLT×10<sup>11</sup>/min) for the Heamonetics e (p value< 0.0001). The product yield for Hemonetics was 4.02 + 0.547 (x  $10^{11}$ /unit). The product yield for Cobe Spectra was 3.97 + 0.428 (x  $10^{11}$ /unit). Therefore, for both cell separators, the final product was similar in terms of platelet yield (p value=0.566). but the Cobe was superior in terms of procedure time and collection rate. These results are summarized in Table-II.

Donor predonation platelet counts ranged from 220-480x10<sup>9</sup> /L. As expected, there was a positive correlation (Figure-1) between product platelet yield and donor platelet count (Pearson correlation coefficient r = 0.81, P<0.0001).

Donor Parameters	Heamonetics MCS 9000	Cobe Spectra
Age (years)	36.12 + 3.16	35.52+2.38
Weight (Kg)	72.74+ 3.56	69.70+3.91
Pre Donation Platelet count (x 10 <sup>9</sup> /L)	314.04 + 62.03	303.78 +49.99

Table-I. Donor parameters for the Heamonetics MCS9000 and Cobe Spectra.

Procedure Parameters	Heamonetics MCS 9000	Cobe Spectra	P- Value
Product Yield (x 10 <sup>11</sup> /unit)	4.02+0.547	3.97+0.428	0.566
Procedure Time (minutes)	81.1+2.757	60.12+3.311	<0.0001
Collection Rate (PLT×10 <sup>11</sup> /min)	0.0519+0.007	0.0655+0.0088	<0.0001

Table-II. Comparison of plateletpheresis product parameters for the Heamonetics MCS 9000 and Cobe Spectra



# DISCUSSION

Platelet concentrate is an invaluable product in the management of the thrombocytopenic patient.<sup>9</sup> Platelets are either prepared as random donor units from whole blood by differential centrifugation, or as single donor units through plateletpheresis.<sup>10,11</sup> An efficient apheresis facility cannot function without well trained staff. They must not only be proficient in operating the cell separators but should also be able to monitor and report any complications to the blood bank physician.

Single donor platelets not only offer the advantage of higher product yield but also protect the recipient from potential alloimmunization that can lead to platelet refractoriness.<sup>12</sup> Furthermore, transmission of disease, which is always a risk in multi-transfused patients, is reduced due to reduction in number of exposures. The cost of single donor platelets is thus higher than random platelet product. This technology employs instruments working on the either intermittent or continuous flow centrifugation. Intermittent flow instruments ensure cell separation over 6-8 cycles or till a therapeutic dose is collected. We analyzed the performance of 2 cell separators, (Haemonetics MCS9000intermittent flow centriguation and TerumoBCTCobe spectra leukoreduction system, version 7- continous flow centriguation) installed at out institute for

### plateletpharesis.13

The donor platelet count, prior to donation, is the most significant variable affecting the platelet count of the final product. A study conducted on 1100 plateletpheresis procedures in 2014 by Mangwana showed this correlation (pearson coefficient 0.58).<sup>14</sup> In a similar study, Guerrero-Rivera calculated the pearson value to be 0.78.<sup>15</sup> The pearson coefficient was 0.8 in our study. Most studies have set a minimal platelet count of 150x10<sup>9</sup>/L as requirement for plateletpheresis. We set a minimal count of 220x10<sup>9</sup>/L as entry criteria to ensure better product yield.

Cobe and other CFC cell separators have the advantages of shorter procedure time. This means a shorter donor turnaround time and higher collection rate. In our study, the separation time with the Heamonetics was 81 min and collection rate  $0.05 \times 10^{11}$ /min. Time with the Cobe was 60 min, with a higher collection rate (p value < 0.0001). A local study by Shaikh et al (2019) has similar observations with the Hemonetics (90 min and collection rate 0.04  $\times 10^{11}$ /min).<sup>16</sup> A study by Tendulkar et al also demonstrated higher collection rates with CFC machines as compared with the IFC.<sup>17</sup> This is in conformance with our study.

Despite some advantages that CFC has over IFC, it has been observed that both types of cell study, both cell separators gave a similar product yield -4.02x 10<sup>11</sup>/unit for Hemonetics and 3.97x10<sup>11</sup>/unit for Cobe (p value<0.0001) Other studies done in 2019 by Sheikh et al and Noha concluded there is no significant difference between yield from CFC and IFC instruments.<sup>18</sup>

Haemonetics MCS9000 offers advantages such as better mobility due to a more compact design and use of single needle for the procedure which may be factor in patient comfort.<sup>19</sup> Although, we did not asses additional parameters, literature review revealed that Haemonetics is similar in terms of providing a leucodepleted product when compared with continuous flow centrifugation (CFC) instruments like the Cobe Spectra. Slight red cell contamination is however seen with Haemonetics product. Furthermore, the extracorporeal volume processed is general higher with IFC machines as compared to CFC. This could pose clinical problems like hypovolemia in particular donor subsets like extreme of age.

CFC separators like the Cobe offer higher yield and a quality product meeting standard leucodepletion criteria by the AABB, i.e, WBC < 5x10<sup>6</sup>/ unit. Two venipuncture sites are employed because the process of withdrawal and reinfusion is carried out simultaneously. The Cobe and other CFC cell separators thus have the advantages of shorter procedure time. Our study conforms to these observations. Additionally the Cobe offers the facility of leucophersis- a feature not available on the Haemonetics.

## LIMITATIONS OF STUDY

We conducted our study on 100 data. A greater sample size would provide a more representative picture on the performance of the 2 cell separators being evaluated. Furthermore, we did not analyze differences in extracorporeal volume between the 2 instruments. This is generally higher with IFC machines and poses the risk of hypovolemia in children and elderly. In the current setting, however, this may not be a problem as many facilities now employ CFC machines instead. Although we selected one IFC and one CFC machine, the results obtained with these might have some differences with other cell separators in the market. One example of this is superior leucodepletion with the newer generation apheresis technology.

The choice of apheresis equipment is determined by feasibility (finances) as well as the spectrum of apheresis procedures in an institute.<sup>20</sup> For example; the Fresenius is employed for preparation of multiple types of apheresis components (plasma, platelets and WBC). Newer generation of cell separators aim to combine the best features of intermittent and continuous flow on one platform. The Spectra Trima is one example of this innovation

# CONCLUSION

CFC machines offer a high quality product with greater efficiency as compared to IFC cell separators.

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