



Comparative assessment of single-donor plateletpheresis by Haemonetics[®] MCS[®] plus and Trima Accel[®]

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Abstract:

BACKGROUND: Single-donor platelets (SDPs) prepared by sophisticated automated equipment offer several advantages over random-donor platelets and are being increasingly used to support thrombocytopenic patients. Different apheresis machines working on the principle of centrifugation are being used worldwide to collect platelets. This retrospective study was done to compare plateletpheresis on two automated cell separators – Haemonetics[®] MCS[®] Plus and Trima Accel[®].

MATERIALS AND METHODS: Data for 100 single-donor plateletpheresis procedures, fifty on each machine, were retrospectively collected and analyzed. Donor characteristics were analyzed by Student's *t*-test and no significant difference was found between the two groups. The parameters compared between the two machines were yield, collection efficiency, blood volume processed, procedure time, acid-citrate-dextrose (ACD) used, leukodepletion achieved, quality control of the products, and adverse donor reactions.

RESULTS: Platelet yield (3.054 ± 0.14 vs. 3.120 ± 0.25), quality control of the platelets, leukodepletion achieved, and donor safety were comparable in both the machines. The blood volume processed (2230.74 ± 227.01 vs. 2452.90 ± 318.61), ACD used during procedure (265.48 ± 43.21 vs. 298.10 ± 53.32), procedural time (55.92 ± 13.00 vs. 68.86 ± 12.64), and the postprocedural decrease in donor count in Trima Accel[®] (183.10 ± 23.99 vs. 161.44 ± 63.47) were significantly less than those in Haemonetics[®] MCS[®] Plus. The median collection efficiency of Trima Accel[®] was found to be greater than Haemonetics[®] MCS[®] Plus (0.000649 vs. 0.000608 , $P = 0.020$).

CONCLUSION: Both Trima Accel[®] and Haemonetics[®] MCS[®] Plus can collect SDPs safely and efficiently. Trima Accel[®] has higher collection efficiency and reduced incidence of citrate-related adverse effects. It also has better potential to optimize productivity due to decreased procedural time.

Keywords:

Haemonetics[®] MCS[®] plus, plateletpheresis, Trima Accel[®]

Introduction

Single-donor platelet (SDP) products prepared by sophisticated automated equipment represent a significant advance in blood component collection. In India, donor plateletpheresis is the most commonly performed apheresis procedure.^[1] Apheresis

is used to obtain platelets from random volunteer donors, patient family members, or donors with human leukocyte antigen or platelet antigen-compatible phenotypes.^[2] Apheresis platelets are being increasingly used to support thrombocytopenic patients.^[2,3] It allows large-volume platelets to be collected and increases the ability to produce optimal components for patients. Platelets collected by apheresis provide a dose equivalent to 6–8 random-donor platelets.^[4] Besides, SDPs offer several

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advantages such as better inventory management, less red blood cell (RBC) and white blood cell (WBC) contamination, as well as limited donor exposure, thereby reducing the risk of transfusion-transmitted infections and alloimmunization.^[2,3,5-7] However, apheresis platelets are not hemostatically different from platelets separated from whole blood.^[8] Different types of cell separators which work on the principle of centrifugation are used for plateletpheresis.^[5,9] The latest-generation apheresis machines have undergone several technical advancements and shown significant progress with respect to collection efficiency, platelet quality, and donor safety.^[10] Some of the machines being used worldwide are Haemonetics® MCS® Plus (Haemonetics Corp, Braintree, MA, USA), COBE® Spectra (Caridian BCT, Lakewood CO), Fresenius AS 104 (Fresenius Medical Care, Walnut Creek, CA, USA), Baxter/Fenwal Amicus (Baxter Healthcare Corp, Deerfield, IL, USA), and Trima Accel® (Caridian BCT, Lakewood, CO). In this study, we have done a comparative assessment of two apheresis machines working on the principle of centrifugal separation of blood. Haemonetics® MCS® Plus is a widely used cell separator used since 1996.^[11,12] It works on the principle of intermittent flow centrifugation and its use for collection of SDPs has improved significantly in the last 20 years.^[13] Trima Accel® is an automated apheresis machine which works on the principle of continuous flow centrifugation.

Materials and Methods

This study was conducted at a tertiary care institute for hepatobiliary disorders in New Delhi. Data for 100 single-donor plateletpheresis procedures were retrospectively collected and analyzed. Fifty procedures were done on Trima Accel® and the other half on Haemonetics® MCS® Plus. The Label Distribution Protocol and software version LN 9000 were used for Haemonetics® MCS® Plus. Software version 6 and 80300 protocol were used for Trima Accel®. Single venous access was used for both the machines. The blood-to-anticoagulant ratio was kept between 9:1 and 10:1.

The donors were selected as per the criteria laid down in the Transfusion Medicine Technical Manual 2003, DGHS, Government of India.^[4] 5-ml whole blood sample was collected pre procedure in ethylenediaminetetraacetic acid for complete blood count, blood grouping, and transfusion-transmitted infectious marker screening. 2-ml sample was collected post procedure for the platelet count. The blood counts were done by Sysmex KX-21 cell counter (Sysmex Corporation, KOBE, Japan). Serological markers of infectivity for hepatitis B and C and HIV were tested by chemiluminescence assay (Architect i 1000SR, Abbott, USA). Rapid card tests were done for malaria

(Omega DX [ASIA] Pvt. Ltd, Maharashtra, India) and syphilis CARBOGEN- Rapid plasma reagin(RPR) card test for syphilis/ carbon antigen for syphilis testing (Cord Clinical Systems, Div of Tulip Diagnostics (P) Ltd, Goa, India) A sample was taken from the sample pouch of the apheresis kit for quality control testing of the product. Quality control parameters tested were platelet count, volume, pH, and swirling movement. The pH was measured by portable pH meter (Accumet AB 15, Fischer Scientific, Singapore) and the residual WBC count was done by Nageotte chamber. Swirling movement of platelets was assessed visually.

The parameters used for comparison of the two machines were total blood volume processed, platelet yield, collection efficiency, acid-citrate-dextrose (ACD) used, procedural time, leukodepletion achieved, postprocedural platelet counts of the donors, donor adverse reactions, and quality control of the platelet products.

The formula used to calculate platelet yield is as follows:

Yield = Product volume × platelet count/μl.

Collection efficiency is calculated using the following formula:

Platelet yield ÷ total platelet processed × 100.

Total platelet processed =
Preplatelet count + postplatelet count ÷ 2 × total blood volume processed × conversion factor.^[14]

Statistical analysis

Categorical variables were presented as proportions, while continuous variables were either presented as mean with standard deviation (SD) or median with range. Comparison of two continuous variables was done by Student's *t*-test for paired data or Mann-Whitney test for unpaired data. Categorical variables were compared by Fisher's exact test or Pearson's Chi-square test. All statistical tools were two tailed and a significance level $P < 0.05$ was used. All statistical tests were performed using IBM SPSS software for Windows version 22 (IBM Corp, Armonk, NY, USA).

Results

Parameters for the two machines Haemonetics® MCS® Plus and Trima Accel® were compared for 100 single-donor plateletpheresis procedures. All the donors were males. The few female donors who had volunteered to donate platelets were deferred due to low hemoglobin, low body weight, or poor venous access. Median age and weight of the donors

were 27.5 years (range: 19–49 years) and 71 kg (range: 58–109 kg), respectively. Mean preplatelet count for the procedures done on Trima Accel® was 246.42 ± 40.27 and on Haemonetics® MCS® plus was 243.92 ± 27.66 . There was no significant difference in the age, weight, and preplatelet count of the donors between the two machines. Mean postplatelet count on Trima Accel® was 183.10 ± 23.99 and on Haemonetics® MCS® plus, it was 161.44 ± 63.47 . The difference was found to be statistically significant ($P = 0.026$) [Table 1].

Based on comparative assessment, we have found that the collection efficiency of Trima Accel® was significantly more than that in Haemonetics® MCS® plus ($P = 0.020$) and the procedure time was significantly less ($P = 0.000$). The blood volume processed by Trima Accel® to achieve the target yield was significantly less than that of Haemonetics® MCS® Plus ($P = 0.000$). Quality control of the platelet products compiled with the standards laid down by AABB for both the machines except that 3% of the platelets collected on Haemonetics® MCS® Plus had a visible RBC contamination. Mean volume of the final product was comparable in both the machines. All the units on both the machines were leukodepleted to below 1×10^6 WBC. The volume of ACD used by Trima Accel® was significantly less than that of Haemonetics® MCS® plus ($P = 0.001$). Platelet yield estimated by the machines was slightly high for both the machines than those calculated in the laboratory. Ninety percent of the procedures done on Trima Accel® achieved target yield, while it was 76% on Haemonetics® MCS® Plus. The target yield achieved was comparable in both the machines. The postprocedural platelet counts decreased significantly in the donors ($P < 0.01$) after each procedure on both machines. The decrease in count was more in Haemonetics® MCS® Plus compared to Trima Accel® ($P = 0.026$) [Table 2]. The criteria laid down by Beuno *et al.* were used to assess citrate toxicity in the donors. Grade 1 reactions (tingling and perioral numbness) were observed in 9% donors on Haemonetics® MCS® Plus and 3% on Trima Accel®. Nearly 8% donors on Trima Accel® and 3% on Haemonetics® MCS® Plus developed hematoma during the procedure. No serious adverse donor reaction occurred during the procedure in any of the machines.

Discussion

Apheresis technology has led to substantial improvement in the quality and productivity of platelets. Use of SDPs is increasing in India due to increased gap between demand and supply of whole blood-derived platelets.^[1] The demand for SDPs in our center is quite high as we cater to a large population of liver disease patients who often present with coagulopathy and thrombocytopenia. SDPs

Table 1: Donor characteristics

Parameter	<i>n</i>	Median	Minimum	Maximum
Age	50	27.5	19	49
Weight	50	71	58	109
Parameter	Machines	<i>n</i>	Mean±SD	<i>P</i>
Preplatelet count	Trima	50	246.42±40.27	0.718
	MCS	50	243.92±27.66	0.718
Postplatelet count	Trima	50	183.10±23.99	0.026
	MCS	50	161.44±63.47	0.028

SD = Standard deviation

Table 2: Procedural characteristics

	Machine	<i>n</i>	Mean±SD	<i>P</i>
Volume processed	Trima®	50	2230.74±227.01	0.000
	MCS®	50	2452.90±318.61	0.000
Yield	Trima®	50	3.054±0.14	0.112
	MCS®	50	3.120±0.25	0.113
Platelet volume	Trima®	50	217.78±13.07	0.060
	MCS®	50	228.42±37.27	0.062
ACD used	Trima®	50	265.48±43.21	0.001
	MCS®	50	298.10±53.32	0.001
Procedural time	Trima®	50	55.92±13.00	0.000
	MCS®	50	68.86±12.64	0.000

	Machine	<i>n</i>	Median	Maximum	Minimum
Collection efficiency	Trima®	50	0.000,649	0.0005	0.0008
	MCS®	50	0.000,608	0.0004	0.0009

SD = Standard deviation, ACD = Acid-citrate-dextrose

are also routinely used in liver transplant surgeries at our institute. We perform plateletpheresis using two cell separators, Haemonetics® MCS® Plus and Trima Accel®. In this study, we have done a comparative analysis of various parameters between the two machines. Although there are various studies in literature on comparison of Trima Accel® with other automated apheresis devices, there are very few studies which compare Trima Accel® and Haemonetics® MCS® Plus. All the donors in our study were males between the age of 19 and 49 years. The mean predonation platelet count of the donors was comparable in both the machines. However, the mean postdonor platelet count was significantly lower for Haemonetics® MCS® Plus than Trima Accel®. Substantial drop in platelet count could be a concern with a predonor count $<200 \times 10^9/L$.^[15] On comparative assessment, we have found that the collection efficiency of Trima Accel® was significantly higher than that of Haemonetics® MCS® Plus. The decreased collection efficiency of Haemonetics® MCS® Plus may be attributed to older version of the machine. It requires greater number of cycles to achieve the target yield of 3×10^{11} . The blood volume processed by Haemonetics® MCS® Plus was also significantly more compared to that of Trima Accel®. However, the collection efficiency is not a very good variable for comparison of apheresis systems.^[3] Differences in the donor population, platelet yield, and postprocedural counts also influence collection efficiency. Hence, the collection efficiency of

the machines in our study may not be comparable with that of previous studies. Procedural time is an important element in apheresis platelet donor retention.^[16] We have observed that the total procedural time of Trima Accel® was significantly less than that of Haemonetics® MCS® Plus. This may be due to the fact that Trima Accel® works on the principle of continuous flow centrifugation and has a high inlet flow rate, while Haemonetics® MCS® Plus works on the principle of intermittent flow centrifugation and the inlet flow rate is slower. The mean volume of the products was comparable in both the machines. All the platelet products on both machines complied with quality standards except that 3% products on Haemonetics® MCS® Plus had visible RBC contamination. The leukodepletion achieved by both the machines was comparable.

The quality of the platelet products in terms of yield was also comparable in both the machines. Shalini *et al.* reported a positive correlation between predonation platelet count and yield.^[17] A direct correlation between pre donation count and yield was also observed by Das *et al.*^[18] In our study, there was no statistically significant difference between the predonation platelet count of donors on the two machines and hence no difference in yield was noted. Nearly 90% of the products on Trima Accel® and 76% of the products on Haemonetics® MCS® Plus achieved the target yield of 3.5×10^{11} . Apheresis procedures are safe with a low incidence of adverse events.^[1,19] It has been reported that the frequency of adverse events in apheresis donors is less than that of whole blood donors.^[20] Rate of complication varies from 0.89% to 4.8% and fatalities are approximately 0.003%–0.02% or <1 for every 10,000 procedures.^[9] Common adverse effects in plateletpheresis donors are hypocalcemia, vasovagal attack, and hematoma.^[21] The most common is hypocalcemia due to citrate anticoagulation.^[19] In our study, 12% of donors on Haemonetics® MCS® Plus and 11% on Trima Accel® had adverse events during the procedure. The incidence of adverse events due to citrate was more for Haemonetics® MCS® plus. This was because volume of ACD used by Trima Accel® was lower than Haemonetics MCS Plus and thus the citrate infused to the donors were significantly low. Factors which influence the rate of citrate reactions include alkalosis due to hyperventilation, rate of ACD infusion, and donor's serum albumin prior to procedure.^[19] Efficient plateletpheresis is defined not only by platelet yield but also by blood volume processed, separation time, and the use of ACD.^[22] Based on our findings, there is significant difference between Trima Accel® and Haemonetics® MCS® Plus in the total blood volume processed, collection efficiency, procedural time, ACD used, and decrease in donor platelet count during the procedure, while the two machines are comparable in terms of platelet yield, platelet product quality, leukodepletion, and donor safety.

Conclusion

Both the machines, Haemonetics® MCS® Plus and Trima Accel®, perform plateletpheresis efficiently and safely. Trima Accel® has better potential to optimize productivity due to decreased procedural time and is more preferred by donors. It also has higher collection efficiency and reduced incidence of citrate-related adverse effects.

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Conflicts of interest

There are no conflicts of interest.

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