Study of Single Donor Platelet (SDP) Preparation by Baxter CS 3000 plus and Haemonetics MCS plus

Col D Swarup*, Brig PS Dhot†, Col S Arora#

Abstract

Background : In plateletpheresis blood is withdrawn from a donor in anticoagulant solution and separated into components. Platelets are retained and the remaining components are returned to the individual.

Methods : The present study was aimed to compare the platelet yield and collection efficiency of Baxter CS 3000 plus and Haemonetics MCS plus cell separators and to study adverse donor reactions. Donors were selected as per the set criteria for single donor platelet (SDP) preparation. Donors' samples for pre donation and post donation platelet count were collected in EDTA and for product counts in the sample pouch attached with apheresis kits. The results were obtained by haematology analyzer. Platelet yield and collection efficiency were calculated.

Result : Results were tabulated for both the cell separators and analyzed. Platelet yield was marginally better with Baxter CS 3000 plus but collection efficiency was better with the Haemonetics MCS plus. Residual white cells were more in single donor platelet concentrate preparation by MCS plus. Adverse donor reactions were similar with both cell separators, in form of mild citrate toxicity and mild to moderate pain at phlebotomy site.

Conclusion : Findings of the present study along with other factors such as less priming time for kit, portability of cell separator, better patient comfort owing to single arm venous access and lesser cost suggest that Haemonetics MCS plus is a better choice as compared to Baxter CS 3000 plus cell separator.

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Key Words : Plateletpheresis; Single donor platelet (SDP)

Introduction

Apheresis is a Greek word that means to separate or remove. In apheresis blood is withdrawn from a donor or patient in anticoagulant solution and separated into components. One or more component is retained and the remaining constituents are returned to the individual [1,2]. Plateletpheresis procedures (single donor platelets) produce an average of the equivalent of 6-10 units ($3-5 \times 10^{11}$ platelets) of random donor platelet concentrates at one time and have now become the main source of platelets in many countries [3].

Recently the use of platelet concentrates has grown steadily due to its employment in chemotherapy protocols. This is specially due to lower alloimmunisation and transmission of viruses to patients afforded by reduced donor exposure [3-7].

The present study was undertaken to compare single donor platelet (SDP) preparation by Baxter CS 3000 plus and Haemonetics MCS plus with a study of adverse donor reactions.

Material and Methods

Forty donors each were subjected to this study by Baxter CS 3000 plus and Haemonetics MCS plus cell separators. All

the donors were replacement donors i.e. friends or relatives of patient.

Donors were selected based on following criteria:

- (i) Weight > 50 kg
- (ii) Age - 18 to 60 years
- (iii) At least three months from last donation/three days from last plateletpheresis
- (iv) Hemoglobin >12.5 gm/dl
- (v) Platelet count > $150 \times 10^3/\text{cmm}$
- (vi) Absence of any illness
- (vii) No consumption of non-steroidal anti-inflammatory drugs for last seven days
- (viii) Negative test for HIV, Hepatitis B, Hepatitis C, Syphilis and Malaria

The apheresis sets used for both the cell separators were as follows :-

For Baxter CS 3000 plus - Fenwal Access closed system apheresis set (Code - 4 R2182, with AMS).

For Haemonetics MCS plus - Extended storage platelet/plasma apheresis set REF 995 E.

After donor selection according to above criteria, the kits were fitted on cell separators and priming was done before performing phlebotomy. Donors were made comfortable on

*CO, 302 Fd Hosp, C/o 99 APO, † Dy Comdt, CH (CC), Lucknow. #Classified Specialist (Pathology), 167 Military Hospital, C/o 56 APO.

donor bleeding couch in a proper airconditioned apheresis room. Samples for platelet count before and after plateletpheresis were collected in EDTA. Samples for post donation count in procedure done on MCS plus were collected from the other arm. Samples for product platelet count and residual WBC count were collected in sample pouch attached with apheresis Kits MCS 3000. The results were obtained by Sysmex Transasia Haematology Analyser.

Platelet yield and collection efficiency were calculated as follows :-

To calculate the total number of platelets in the final product, the following equation is used.

$$\text{Platelet yield} = \frac{\text{Product (ml)} \times \text{Product count (platelet/ ul)} \times \text{Conversion factor (1000 ul/ ml)}}{\text{volume (ml)}}$$

To calculate collection efficiency, total platelet processed is to be calculated by following calculation:-

$$\text{Total platelet processed} = \frac{\text{Pre + Post count (Platelets/ul)} \times \text{Total blood volume processed (ml)} \times \text{Conversion factor (1000ul/ml)}}{2}$$

$$\text{Collection efficiency} = \frac{\text{Platelet yield}}{\text{Total platelet processed}} \times 100 \%$$

Results

Forty donors each subjected to plateletpheresis by Baxter CS 3000+ as well as Haemonetics MCS + were all voluntary donors or replacement donors (relatives/ friends of patients). All the donors were male and their age group varied from 20 years to 49 years. Haemoglobin of the donors varied between 12.8 gm/dl to 17.5 gm/dl and platelet count between $150 \times 10^3/\text{cmm}$ to $623 \times 10^3/\text{cmm}$. Data of both the procedures are tabulated in Table 1.

Table 1

Platelet pheresis : Platelet yield and collection efficiency

No of procedures	Baxter CS 3000 + 40	Haemonetics MCS + 40
Donor's platelet count x $10^3/\text{cmm}$		
Range	166-623	150-450
Mean	257.05	244.725
Product platelet count x $10^3/\text{cmm}$		
Range	611-2631	764-2118
Mean	1241.35	1231.05
Platelet yield x 10^{11}		
Range	2.7-7.1	2.3-5.8
Mean	3.58	3.33
>3 x 10^{11}	35 (87.5%)	27 (67.5%)
Product volume (ml)		
Range	210	198-339
Mean	210	235.92
Volume processed (ml)		
Range	2349-4014	1829-3388
Mean	3314.15	2501.97
Collection efficiency %		
Range	33.19-61.25	36.25 - 84.90
Mean	49.90%	65.49%
>50%	23 (57.5%)	39 (97.5%)
Time taken in procedure (Min)		
Range	55-90	54-102
Mean	76.65	71.47

The time taken per procedure was comparable with both the cell separators. Average time was 76.6 (range 55 - 90) minutes for Baxter CS 3000 plus and 71.47 (range 54 - 102) minutes for Haemonetics MCS plus. One procedure was terminated after 45 minutes due to lack of smoothness in return flow. Product platelet count was $1241.35 \times 10^3/\text{cmm}$ (range 611×10^3 to $2631 \times 10^3/\text{cmm}$) for Baxter CS 3000 plus and $1231.05 \times 10^3/\text{cmm}$ (range $764 \times 10^3/\text{cmm}$ to $2118 \times 10^3/\text{cmm}$) for Haemonetics MCS plus. The platelet yield was marginally better with an average of 3.58×10^{11} by Baxter CS 3000 plus as compared to an average yield of 3.33×10^{11} with Haemonetics MCS plus. The collection efficiency of Haemonetics MCS plus was better with an average of 65.49% as compared to Baxter CS 3000 plus with an average of 49.90%. Thirty nine (97.5%) cases by MCS plus showed collection efficiency of >50% as compared to 23 (57.5%) cases by CS 3000 plus.

Residual red blood cell (RBC) count as well as residual white blood cell (WBC) count of the SDP prepared by Haemonetics MCS plus were more as compared with Baxter CS 3000 plus (Table 2). Range of RBC count was $0.01 \times 10^6/\text{cmm}$ to $0.21 \times 10^6/\text{cmm}$ with an average of $0.06 \times 10^6/\text{cmm}$ for Baxter CS 3000 plus and $0.03 \times 10^6/\text{cmm}$ to $0.5 \times 10^6/\text{cmm}$ with an average of $0.154 \times 10^6/\text{cmm}$ for Haemonetics MCS plus. Similarly range of residual WBC was 0 to $1.2 \times 10^3/\text{cmm}$ with an average of $0.29 \times 10^3/\text{cmm}$ for Baxter CS 3000 plus and 0 to $5.2 \times 10^3/\text{cmm}$ with an average of $0.77 \times 10^3/\text{cmm}$ for Haemonetics MCS plus. Out of 40 platelet pheresis done by Haemonetics MCS plus, residual WBC in one case was $5.20 \times 10^3/\text{cmm}$, between $1.0 \times 10^3/\text{cmm}$ to $2.70 \times 10^3/\text{cmm}$ in eight cases and less than 1.0×10^3 in remaining 31 cases. Apheresis product by Baxter CS 3000 plus showed better leucoreduction with only three cases with residual WBC between 1.0×10^3 cmm to $1.2 \times 10^3/\text{cmm}$ and 37 cases showing less than 1.0×10^3 cmm residual WBCs.

Most of the donors did not feel any discomfort and their procedures were uneventful but there were minor citrate toxicity symptoms as enumerated in Table 3. In one donor on MCS plus, the flow in returning of blood was not smooth and procedure was stopped after 45 minutes with 1829 ml blood volume processed.

Few donors exhibited adverse reaction in form of circummoral paresthesia and mild to moderate pain at phlebotomy site (Table 3). Five (12.5%) donors on Baxter CS 3000 plus and four (10%) donors on Haemonetics MCS plus felt paresthetia over face and similar number of donors felt mild to moderate pain respectively. Thus there may not be any obvious differences in both the cell separator procedures,

Table 2

Residual WBCs and RBCs in final product (i.e SDP)

	Baxter CS 3000 +	Haemonetics MCS +
Residual WBC Count x $10^3/\text{cmm}$		
Range	0-1.2	0-5.2
Mean	0.29	0.77
Residual RBC Count x $10^6/\text{cmm}$		
Range	0.01-0.21 (0.35-7.35 ml)	0.03-0.5 (1.17-19.50 ml)
Mean	0.06 (2.10 ml)	0.154 (5.85 ml)

Table 3**Adverse donor reactions**

	Baxter CS 3000 +		Haemonetics MCS +	
	n	(%)	n	(%)
Citrate Toxicity	5	12.5	4	10
Circum oral paresthesia				
Venipuncture related				
Pain at phlebotomy site	5	12.5	4	10
Mild	4		3	
Moderate	1		1	
Haematoma	—		—	
Nausea/ vomiting	—		—	
Syncope	—		—	

as regards the adverse effects. None of the donor experienced any other side effects such as hematoma formation, nausea, vomiting, muscle tightening, tetany or syncope.

Discussion

In the present study 40 cases each of single donor plateletpheresis were performed by CS 3000 plus (Baxter) and MCS plus (Haemonetics). Donor selection was as per the laid down criteria. The donors were distributed randomly for plateletpheresis by both the cell separators.

The average time taken per procedure was similar with both machines being 76.6 minutes and 71.47 minutes for CS 3000 plus and MCS plus respectively. Product platelet count was better with Baxter CS 3000 plus, $1241.35 \times 10^3/\text{cmm}$ as compared to $1231.05 \times 10^3/\text{cmm}$ with Haemonetics MCS plus. The product volume with CS 3000 plus was 210 ml as compared to 235.92 ml with MCS plus. Similar findings were shown by Patel et al who attributed higher platelet count by Baxter due to low product volume [6].

In the present study platelet yield was marginally better with CS 3000 plus with an average of 3.58×10^{11} as against 3.33×10^{11} with MCS plus. More cases on CS 3000 plus showed higher than 3×10^{11} platelet yield i.e. 87.5 % as compared to 67.5% cases with MCS plus. Donors with higher pre-donation platelet count showed better yield with both machines with minor variations. Vavic et al [8] and Patel et al [6] have shown correlation of better platelet yield with better pre-donation platelet count and more total processed blood volume. According to Lai et al [9] there was no difference in platelet yield by Amicus, CS 3000 plus and MCS plus, but Patel et al [6] showed better platelet yield with MCS plus as compared to CS 3000 plus.

In the present study collection efficiency was higher with MCS plus cell separator at an average of 65.49% as compared to CS 3000 plus, with 49.90%. Thirtynine (97.5%) cases showed >50% collection efficiency with MCS plus as compared to 23 (57.5%) cases with CS

3000 plus. Stiegler et al [10], while comparing MCS plus and Cobe - Trima have shown higher collection efficiency with MCS plus. Findings of Patel et al [6] are also similar to our results.

In the present study residual WBC were higher with Haemonetics MCS plus with a mean value of $0.77 \times 10^3/\text{cmm}$ as compared to CS 3000 plus with a mean value of $0.29 \times 10^3/\text{cmm}$. Final product in one case on MCS plus showed residual WBC count of $5.2 \times 10^3/\text{cmm}$, which could be due to clumping of WBCs. If this case is excluded the average residual white blood cell value by MCS plus was $0.66 \times 10^3/\text{cmm}$. 37 cases by CS 3000 showed residual WBC count of less than $1.0 \times 10^3/\text{cmm}$ as compared to 31 cases by MCS plus. Better leucoreduction can be achieved by adopting newer protocols with inline filtered SDP preparation [11].

Though naked eye appearance of the final product did not show reddish or pink colour, it showed an average red cell count of 0.15×10^6 per cmm (5.85 ml) with MCS plus and $0.06 \times 10^6/\text{cmm}$ (2.10 ml) with CS 3000 plus. Hong Ying et al [12] have opined of hyperlipidemia or unclear blood stream as the reasons causing apheresis platelet to be contaminated with red blood cells.

In the present study the adverse donor reactions noted were mild citrate toxicity in form of circumoral paresthesia in 12.5% of cases with Baxter CS 3000 plus and 10% cases with MCS plus. A similar number of donors had mild to moderate pain at venipuncture site. No severe adverse donor reaction were noted with either of the cell separator. Thus, apheresis procedure is a safe procedure. Though it takes much more time than whole blood donation the longer collection time allows better fluid equilibration and a lower risk of hypovolaemia or syncope. Other workers [13-16], have also reported plateletpheresis by using cell separators as a safe procedure.

The other consideration in comparing the Baxter CS 3000 plus and Haemonetics MCS plus is the time taken in setting the kit and priming before phlebotomy. As observed at our centre, it takes approx 20-25 minutes with CS 3000 plus but less than five minutes with MCS plus. Therefore when large number of procedures are to be performed, MCS plus is a better choice. In our study the cost of kits per procedure was Rs 6696/- with Baxter CS 3000 plus as compared to Rs 4788/- with Haemonetics MCS plus.

This study shows that Haemonetics MCS plus is a better cell separator as compared to Baxter CS 3000 plus. Although the apheresis should be performed in apheresis room, portability of MCS plus is an added advantage. Patient comfort owing to single arm venous access and cost factor are also important considerations

to recommend MCS plus as a better choice as compared to CS 3000 plus for plateletpheresis as well as plasma pheresis in transfusion medicine, haematology, oncology and other departments of hospitals.

Conflicts of Interest

None identified

Intellectual Contribution of Author

Study Concept : Col D Swarup, Brig PS Dhot

Drafting & Manuscript Revision : Col D Swarup, Brig PS Dhot, Col S Arora

Statistical Analysis : Col D Swarup

Study Supervision : Col D Swarup, Brig PS Dhot, Col S Arora

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