Comparison study among three blood cell separators

Paul Höcker, Irena Qendro

Department of Transfusion Medicine, University Hospital, Vienna, Austria

Introduction

After the introduction of the new AS.TEC204 cell separator, we performed a prospective study to compare the platelet collection efficiency of three different types of cell separators: Amicus™ (Baxter Healthcare Corporation, Fenwal Division, Deerfield, IL, USA), Spectra™ (Cobe BCT Inc., Lakewood, CO, USA) AS.TEC204 (Fresenius, Dreieichen, Germany). A lot of comparison studies among cell separators are done by using different donors. The use of different donors allows the quality of the product to depend not only on the cell separator but also on the variability among different donors. Therefore, in our study we used identical donors, which by minimizing the intraindividual variability like platelet activation state and platelet count before donation, allows the quality of the product (i.e. the platelet yield) and WBC contamination to depend more on the cell separator. The use of identical donors makes also possible a better investigation of the citrate side effects because different donors react in different ways towards the citrate effects. The aim of the study was to compare, from one side, the efficiency of the cell separators in producing platelet concentrates by evaluating the platelet yield, separation efficiency and WBC contamination, and, from the other side, the donor comfort by evaluating the procedure time and the ACD side effects.

Materials and methods

After fulfilling the national guidelines for haemapheresis and giving written informed consent, 11 male volunteer donors with a total blood volume of more than 4,500 mL and platelet counts above 4,500 mL/L, underwent plateletpheresis on three different blood cell separators with an interval of 14 days between each plateletpheresis.
To establish comparability among the three cell separators a fixed endpoint of 4,800 mL was set. All the platelet collections were performed with the double needle procedure.

**Amicus™**: The program version 2.78 was used. For the Amicus™ procedures, the blood was mixed with ACD-A at a ratio 9:1 and processed at a mean whole blood flow rate of 58.1 mL/min. Platelet and WBC counts of the product were determined four hours after the end of the donation procedure (the products were rested for two hours at room temperature, and then agitated for two hours, as recommended from the manufacturer).

**Spectra™**: The program LZT/LRS (Leukocyte Reduction System) software version 5.1 was used. For the Spectra™ collections the endpoint of 4,800 mL was set by increasing or decreasing the time. ACD-A was added at a rate of 1 mL/min/L of donor total blood volume. With this program the AC/blood ratio is reduced from 1:7 to 1:9 to 1:11 during the procedure. Therefore the mean whole blood flow rate was automatically increased from 47.0 to 74.8 mL/min. The samples for the determination of the platelet and WBC counts of the obtained product were taken after one hour of resting time (following the recommendations of the manufacturer).

**AS.TEC 204**: The program Plt-5d V 1.1.3 and the apheresis set with an inline leucodepletion filter were used for the AS.TEC204 procedures. With this cell separator for setting the endpoint of 4,800 mL, the yield was increased or decreased. The mean whole blood flow rate was 60 mL/min. The product sampling was done after one hour of resting time in room temperature.

All the obtained products were observed for visible aggregates at the end of the donation procedure. Donor peripheral blood counts, both before and after donation, and the product platelet and WBC counts were determined by electronic particle counting (Cell DYN 3500, ABBOTT, Santa Clara, CA). The efficiency of the platelet collection was calculated with the following formula:

\[
\text{Efficiency} = \frac{\text{Plt yield} \times 10,000}{\text{TPBV} \times \frac{\text{Plt pre} + \text{Plt post}}{2}}
\]

Where:
- Plt yield = platelet yield of the evaluated product
- Plt pre = platelet count before donation
- Plt post = platelet count after donation
- TPBV = total processed blood volume, calculated by taking the volume of ACD from the endpoint volume.

For the statistical evaluation an Anova (Duncan’s Multiple Range Test) was used. A $p$-value of $< 0.05$ was considered statistically significant.

**Results**

Amicus™ achieved a higher platelet yield than Spectra™ and a significantly higher one than AS.TEC204 by processing the same amount of blood. The predicted yield was achieved in 30% of the Amicus™ procedures, and in 50% of the AS.TEC204 procedures, whereas the Spectra™ always achieved the predicted yield, except for one case. The separation efficiency was significantly higher in the Amicus™ device than in the other devices. The donors mean predonation and post donation platelet counts were equivalent.

WBC contamination in the platelet concentrates obtained from Spectra™ and AS.TEC204 products was respectively $3.16 \pm 1.53 \times 10^6$ and $3.72 \pm 2.16 \times 10^6$. The percentage of the products with WBC contamination of $<5 \times 10^6$ was 90% for Spectra™ and 70% for AS.TEC204. The Amicus™ showed a higher but not statistically significant WBC contamination.

The procedure time needed by Spectra™ was significantly lower (78.7 min, vs. 85.6 AS.TEC204 and 89.6 Amicus™).

From the evaluated donations there was only one with technical problems by Amicus™ cell separator, whereas there was no problem during the donations by Spectra™ and AS.TEC204. The data obtained from this donor in all three-cell separators are not included in the comparison that is shown in the following tables.

The donors found all the donation procedures acceptable. The donation by AS.TEC204 was found as louder from 4/11 donors.

Comparisons of the obtained results are presented in Table 1 and Table 2.

**Discussion**

This study was performed by using a fixed endpoint and identical donors in order to make possible the
Amplificazione PCR gene RHD in Rhnull

P Höcker, I Qendro

comparison of the efficiency of these three blood cell separators in producing platelet concentrates. Our results are in accordance with the results reported before1-5. Amicus™ cell separator achieved the highest platelet yield and separation efficiency. Amicus™ achieved a significantly higher separation efficiency than the others while the mean platelet count of our donors before donation by AmicusTM was equal with the mean platelet count before donation by the other two cell separators, showing in this way that Amicus™ can achieve high separation efficiencies without needing for this higher platelet precounts.

Another important issue is the percentage of the collections with platelet count of ≥ 3 x 10^6. The Standards of the American Association of Blood Banks6 require that at least 75% of the collections have ≥ 3 x 10^11. When calculating the frequencies of yields of 3x10^6 we found that all three cell separators far surpassed the standards of AABB because 100% of the Amicus™ and Spectra™ collections had platelets values of > 3x10^11, whereas there was only one AS.TEC204 collection with platelet value below this standard. The high platelet yield provided from the Amicus™ device, made possible a more frequent “splitting” of the components.

The mean WBC contamination was not significant in this study. Considering the value of 1x10^6 as our threshold for subsequent filtration we found that 40% of the Amicus™ products needed subsequent filtration. It is now known that the subsequent filtration results in loss of significant percentage of platelets (7-30%). From this point of view, the advantage of the Spectra™ cell separator was that only one of the Spectra™ products needed subsequent filtration, avoiding in this way the risk of platelet loss. From the evaluated AS.TEC204 products there was none that needed subsequent filtration, but from the filtration with the inline filter there was a loss of about 6% of platelets.

Time is considered as a very important parameter not only for the apheresis center but also for the retention of the donors7. In our study the Spectra™ device was slightly quicker than the two other devices, and this might be due to a faster blood flow rate used by Spectra™. From the evaluated products there were observed platelet aggregates in five cases of the Spectra™ collections and this might be due to the smaller volume collect by Spectra™ device. The observed aggregates were completely reversible by gentle agitation and the small volume of the platelet concentrate collected by Spectra™ had the advantage of the use in patients who couldn’t tolerate additional intravascular volume, i.e small children.

The AS.TEC204 used significantly more ACD-A than the others but the hypocalcaemic symptoms observed in the donors were not significant. The donors described as more severe the symptoms by Spectra™ donation, and this perhaps occurred because of the faster whole blood flow rate used by Spectra™. The ACD-A side effects were always observed in the same donors.

In conclusion, we prospectively compared three different types of cell separators by using identical donors and by fixing the endpoint with respect to platelet yield,

### Table II: comparative results of 30 plateletpheresis procedures (10 in each cell separator)

<table>
<thead>
<tr>
<th></th>
<th>Amicus™</th>
<th>Spectra™</th>
<th>AS.TEC204</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plt pre (G/L)</td>
<td>242.40 (±44.76)**</td>
<td>263.10 (±47.63)</td>
<td>254.90 (±47.31)</td>
<td>NS</td>
</tr>
<tr>
<td>Plt post (G/L)</td>
<td>166.00 (±30.99)</td>
<td>183.60 (±29.59)</td>
<td>180.70 (±32.50)</td>
<td>NS</td>
</tr>
<tr>
<td>Procedure Time (min.)</td>
<td>89.50 (± 9.90)</td>
<td>78.70 (±4.81)</td>
<td>85.60 (±1.65)</td>
<td>***A:S=0.0012 A:AS=0.02364 S:AS=0.00006</td>
</tr>
<tr>
<td>Used ACD-A (L)</td>
<td>0.53 (±0.04)</td>
<td>0.48 (±0.02)</td>
<td>0.60 (±0.05)</td>
<td>A:S=0.0170 A:AS=0.0002 S:AS=0.00006</td>
</tr>
<tr>
<td>Platelet Yield (x 10^11)</td>
<td>5.43 (±0.75)</td>
<td>4.74 (±1.11)</td>
<td>4.36 (±1.02)</td>
<td>A:S=NS A:AS=0.0264 S:AS=0.3947</td>
</tr>
<tr>
<td>Efficiency (%)</td>
<td>63.22 (±10.22)</td>
<td>47.32 (±7.19)</td>
<td>47.18 (±5.91)</td>
<td>A:S=0.0002 A:AS=0.0002 S:AS=NS</td>
</tr>
<tr>
<td>Mean WBC (x10^6) abs.</td>
<td>5.51 (±3.71)</td>
<td>3.16 (±1.53)</td>
<td>3.72 (±2.16)</td>
<td>NS</td>
</tr>
</tbody>
</table>

* G = "Giga" 10^9
** The values showed in the table are means and in parenthesis the standard deviations
*** A:S—Comparison between Amicus™ and Spectra™
A:AS—Comparison between Amicus™ and AS.TEC204
S:AS—Comparison between Spectra™ and AS.TEC204
collection efficiency WBC contamination and procedure time. All three cell separators provided platelet concentrates with high yields and low WBC contaminations and are therefore useful for routine single donor plateletpheresis.

Summary

Three blood cell separators (Amicus<sup>TM</sup>; Cobe Spectra<sup>TM</sup>; AS.TEC204 Fresenius,) were prospectively compared in regard to platelet yield, collection efficiency, procedure time and WBC contamination by using identical donors and a fixed endpoint.

Amicus<sup>TM</sup> showed a higher collection efficiency and platelet yield than the two others. The collection efficiency was significantly higher towards both of the other cell separators (63.22%±10.22 vs. 47.32%±7.19 Spectra<sup>TM</sup> and 47.18 %±5.91 AS.TEC204) whereas the platelet yield was significantly higher only towards AS.TEC204. The obtained yield results (x10<sup>11</sup>) were: 5.43±0.75 Amicus<sup>TM</sup>; 4.74±1.11 Spectra<sup>TM</sup> and 4.36±1.02 AS TEC204.

Spectra<sup>TM</sup> needed significantly less time by processing, with a faster blood flow. The time results were: Amicus<sup>TM</sup> 89.5min.±9.90, Spectra<sup>TM</sup> 78.7 min±4.81 and AS.TEC204 85.6min±1.65.

The WBC contamination of the products obtained by the three cell separators was not statistically significant. The mean values of the WBC contamination were as following: 5.51±3.71x10<sup>6</sup> Amicus<sup>TM</sup>; 3.16±1.53 Spectra<sup>TM</sup>; 3.72±2.16 AS.TEC204. Macroscopically visible aggregates were observed only in five Spectra<sup>TM</sup> collections, but they were completely reversible.

We found that all three blood cell separators are able to produce platelet concentrates with high yields and low WBC contamination.

References