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Comparison of Apheresis Machines - COMTEC and Amicus, Based on Machine Parameters and Product Quality

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Abstract: ***Background: diverse array of apheresis devices is currently available on the market for platelet apheresis. This study conducts a comparative quality including platelet (PLT) yield, RBC contamination, white blood cell (WBC) content, Post Procedure. Material and Methods: Donors undergoing plateletpheresis were randomly assigned to one of two groups (Amicus or COM.TEC cell. Results: In the pre-apheresis procedure setting, there were no significant differences in donor characteristics (sex, age, quite similar. The blood volume processed to, achieve a target PLT yield of ≥3 × 10¹¹ was significantly t higher products collected with the Amicus and 94% of those with the COM.TEC met the target PLT yield of >3.3 × 10⁶. However, the collection rate was significantly higher with the Amicus compared to the COM.TEC (0.079 ± 0.012 × 10¹¹ vs. 0.067 ± 0.008 × 10¹¹ PLT/min, p < 0.003). Conclusion: Both instruments efficiently collected platelets, with consistent leukoreduction achieved tin both cases.***

Keywords: Plateletpheresis, Apheresis, Amicus, COM.TEC, Cell separator

1. Introduction

- Plateletpheresis presents several advantages for blood donation and transfusion practices: -
- Efficient Blood Use: It allows for the selective collection of large quantities of specific components, optimizing blood resources.
- Increased Donation Frequency: Donors can give more often due to the targeted nature of the procedure.
- Reduced Laboratory Processing: It eliminates the need for unnecessary separation of components in the lab.
- Lower Risk of Disease Transmission: By minimizing donor exposures, it decreases the chance of disease spread and reduces human leukocyte antigen (HLA) alloimmunization.
- Effective Treatment for Alloimmunized Patients: Plateletpheresis is a viable option for patients who have developed alloantibodies, and products can be labeled as "leukoreduced" without further processing.
- Despite advancements in apheresis technology, challenges persist, such as: - Procedure Duration: The time required for plateletpheresis can be lengthy.
- Donor Discomfort: The citrate anticoagulant used during collection may cause discomfort. These issues drive ongoing innovations in apheresis devices.
- Currently, various plateletpheresis machines are available, and multiple studies have evaluated different cell separators. However, there is limited data comparing the Fenwal Amicus and Fresenius COM.TEC cell separators. This study aims to compare the Fenwal Amicus cell separator (Baxter Healthcare) with the Fresenius COM.TEC cell separator (Fresenius Hemo-Care GmbH). We focused on key performance indicators such as processing times, platelet yields, separation efficiencies, and white blood cell content.

2. Materials and Methods

The study included healthy volunteer donors who met the eligibility criteria according to the standard guidelines established by the *American Association of Blood Banks* [14, 15]. Donors were recruited between December 2023 andtDecember 2024. Eligibility for donation of a single unit (≥3 × 10¹¹ platelets) was based on the following criteria:

1) Age 18–60 years,
2) Pre-apheresis peripheral blood platelet (PB PLT) count ≥ 150 × 10⁹/L,
3) Hemoglobin (Hb) level ≥ 12.5 g/dL,
4) Body weight ≥ 50 kg,
5) Negative tests for HIV, hepatitis B surface antigen, hepatitis C, and syphilis and malaria
6) Absence of any illness,
7) Donor in good health
8) Adequate venous access,
9) At least 1 month since the last whole blood donation,
10) At least 3 days / 72 hrs since the last plateletpheresis donation.
11) No use of non-steroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid (aspirin) in the past 7 days [16].

The study was approved by the Institutional Review Board, and written informed consent was obtained from all donors after the risks of the were explained in detail

3. Instruments

- A single Fenwal Amicus instrument with software version 2.52 (Baxter Healthcare, Deerfield, IL, USA) was used. A single venous access with a plateletpheresis kit was used

per the manufacturer's recommendation. The parameters of the Amicus device were as follows: whole blood flow 55–80 ml/min, interface set point 0.60, and anticoagulant/whole blood ratio 1:8–11. The second cell separator used for PLT collection was the blood cell separator COM.TEC, software version 4.0 (Fresenius HemoCare GmbH, Bad Homburg, Germany).

- Per the manufacturer's recommendations, we used a single venous access with a S5L kit in a single-needle procedure (program PLT5d SN). The machine parameters were as follows: whole blood flow 50–75 ml/min, interface set point 33, and anticoagulant/whole blood ratio 1:8–12. The following data were entered into the cell separator program for both instruments: donors' height, weight, sex, hematocrit (Hct) and pre-apheresis PB platelet count. The processed blood volume to reach the target PLT yield (≥3 × 1011) was determined by both instruments. No additional post-procedure processing or filtration to obtain leukoreduced products was performed on either instrument.

4. Operational Variables

During each plateletpheresis procedure, we tracked several key operational variables: - Procedure Time: Total duration of the procedure.

- Processed Blood Volume: Amount of blood needed to achieve the target platelet yield. - Flow Rate: Speed at which blood is processed during the procedure.
- ACDA Volume: Quantity of acid citrate dextrose-A anticoagulant used.
- Platelet Yield Variables After allowing the platelet collection bag to rest for one hour without agitation, we collected 2 ml samples from the bag for laboratory analysis.

The following parameters were evaluated:

- Volume, Platelet Count (PLT)
- White Blood Cell Count (WBC)
- Red Blood Cell Count (RBC)
- Swirling: Assessed visually- Ph

This streamlined approach ensures clarity and focus on critical data during plateletpheresis.

5. Result

The study compares the Amicus and COM.TEC instruments in terms of donor characteristics, pre- and post-apheresis blood variables, plateletpheresis operational variables, product variables, and adverse effects. Here's a summary of the findings:

Donor Characteristics (Table 1)

- **Age**: Median age was similar between the two groups (Amicus: 30 years, COM.TEC: 29 years).
- **Gender**: The gender distribution was almost identical, with 478 males and 22 females in the Amicus group and 481 males and 19 females in the COM.TEC group.

Weight, Height, and TBV

Characteristics	Amicus (n= 32)	Com. TEC (n= 32)	P Value*
Male/ Female	478/ 22	481/19	0.644
Age (years), median (range)	30 (18- 43)	29 (21- 49)	0.146
Weight (kg), mean ± SD	71.9 ± 10.4	72.4 ± 71	0.946
Height (cm), median (range)	169 (155-185)	170 (163- 180)	0.839
TBV (ml), mean ± SD	5,244 ± 778	5,297 ± 464	0.696

Pre- and Post-Apheresis Blood Variables (Table 2)

- **Pre-apheresis Platelet Count (PLT)**: The pre-apheresis PLT count was significantly higher in the COM.TEC group (203 × 10^3/µl) compared to the Amicus group (193 × 10^3/µl) (p = 0.035).
- **Post-apheresis Platelet Count**: The Amicus group had a significantly lower post-apheresis PLT count (140 × 10^3/µl) compared to the COM.TEC group (161 × 10^3/µl) (p = 0.019).

Other variables, including Hb, Htc, WBC counts, and platelet loss percentages, showed no significant differences.

Characteristic	Amicus	COM.TEC	P Value
Pre-apheresis WBC (× 10^3/µl), median (range)	6.85 (4.4–11.2)	7.45 (5.1–10.4)	0.08
Post-apheresis WBC (× 10^3/µl), median (range)	6.5 (3.9–9.7)	6.7 (4.0–10.0)	0.646
WBC loss (%), median (range)	11.7 (0–36.2)	15 (0–25)	0.05
Pre-apheresis Hb level (g/dl), mean ± SD	15.3 ± 1.4	15.7 ± 1.3	0.542
Post-apheresis Hb level (g/dl), mean ± SD	14.1 ± 1.5	14.2 ± 1.5	0.882
Hb loss (%), median (range)	6.7 (0–9.3)	6.5 (3.3–13.6)	0.605
Pre-apheresis Htc level (%), mean ± SD	44.1 ± 2.7	43.7 ± 3.2	0.258
Post-apheresis Htc level (%), mean ± SD	41.8 ± 3.1	41.4 ± 4.2	0.979
Htc loss (%), median (range)	5.4 (2.2–18.4)	5.8 (0–9.9)	0.171
Pre-apheresis PLT count (× 10^3/µl), median (range)	197 (159–313)	227 (180–248)	0.025*
Post-apheresis PLT count (× 10^3/µl), median (range)	147 (105–206)	164 (109–237)	0.029*
PLT loss (%), median (range)	31 (19–40)	23 (3–39)	0.07

Plateletpheresis Operational Variables (Table 3)

- **Blood Volume Processed**: The COM.TEC processed significantly more blood (3,497 ml) compared to the Amicus (2,866 ml) (p < 0.001).
- **Flow Rate**: The Amicus had a higher median flow rate (63 ml/min) compared to the COM.TEC (52 ml/min) (p < 0.001).
- **ACD-A Volume**: The COM.TEC required significantly more ACD-A (378 ml) than the Amicus (313 ml) (p < 0.001).
- **Separation Time**: The COM.TEC required significantly more time (59 min) for the procedure compared to the Amicus (46 min) (p < 0.001).

Characteristic	Amicus	COM.TEC	P Value
Blood volume processed (ml), median (range)	2,866 (2,500–3,500)	3,497 (2,742–4,139)	<0.001
Flow rate (ml/min), median (range)	63 (55–75)	52 (50–65)	<0.001
ACD-A volume (ml), median (range)	313 (210–341)	378 (294–407)	<0.001
Separation time (min), median (range)	47 (37–58)	63 (48–72)	<0.001
Product volume (ml), median (range)	289 (260–340)	306 (300–304)	<0.001

Plateletpheresis Product Variables (Table 4)

- **Platelet Yield per Blood Volume Processed**: The Amicus had a significantly higher yield per blood volume processed (0.43) compared to the COM.TEC (0.34) ($p < 0.001$).
- **PLT Yield/BAG**: No significant difference in the platelet yield per bag between the two instruments.
- **Collection Rate**: The Amicus had a significantly higher collection rate (0.079×10^{11} PLT/min) compared to the COM.TEC (0.008×10^{11} PLT/min) ($p < 0.001$).
- **RBC Count/BAG**: The RBC count per bag was significantly lower in the Amicus group compared to the COM.TEC ($p = 0.007$).
- **WBC Count/BAG**: No significant difference in the WBC count per bag between the two instruments.

Adverse Effects

Citrate-related Mild Toxicity: Citrate-related toxicity occurred more frequently in the COM.TEC group (42 donors) compared to the Amicus group (34 donors), likely due to the higher volume of ACD-A used during the procedure. All adverse effects were managed with decreased flow rates and/or oral calcium supplementation.

Table 4: Plateletpheresis Product Data

Characteristic	Amicus	COMTEC
Swirling Percent	100	100
PLT Yield/ bag ($x10^{11}$); median (range)	3.39 (2.84- 4.03)	3.33 (2.87- 3.94)
Number of PLT yield >3.3 x 10^{11}/bag	465/ 500 (93%)	445/ 500 (89%)
PLT yield/ blood volume processed	0.42	0.33
WBC count/ bag ($x10^6$); Median (range)	0.30 (0.30- 1.20)	0.57 (0.26- 1.43)
Number of yield with WBC <1 $x10^6$	470 (94%)	445 (87%)
RBC count/bag ($x10^6$); mean $\pm$ SD	4.3 $\pm$ 10.2	13.18 $\pm$ 15.18

6. Conclusion

- **Amicus vs. COM.TEC**: The Amicus generally performed better in terms of flow rate, platelet yield per blood volume processed, and collection rate. However, the COM.TEC processed more blood and required more ACD-A. The operational variables such as separation time and blood volume processed were significantly higher with the COM.TEC.
- **Adverse Effects**: Mild citrate toxicity was more common with the COM.TEC, likely due to the larger volume of ACD-A used. Overall, the Amicus demonstrated better efficiency in terms of platelet yield and collection rate, while the COM.TEC required more time and processing volume.
- **Both the COM.TEC and Amicus are effective for plateletpheresis**, with both devices meeting the standards for **leukoreduction** and achieving **consistent platelet yield**. However, the **Amicus** has a clear advantage in terms of **shorter procedure times** and **higher efficiency** for **platelet yield per blood volume processed**. The **COM.TEC** may still be valuable in specific settings, especially where slight improvements in collection efficiency are prioritized.
- **The Amicus**'s ability to complete the procedure in less time, coupled with its slightly higher recovery rate and lower citrate consumption per minute, makes it the preferred choice in environments where speed and efficiency are essential.
- **Citrate-related adverse effects** were minimal and not clinically significant for either instrument, though the **COM.TEC** saw slightly more cases, which could be attributed to its higher ACD consumption.

7. Implications

Productivity (time efficiency) is a critical factor in selecting plateletpheresis devices, and while the **COM.TEC** offers similar platelet yields, the **Amicus** excels in speed and overall efficiency.

8. Discussion

This study provides a detailed comparison of two widely used plateletpheresis instruments: **COM.TEC** and **Amicus**, analyzing key parameters such as separation time, platelet (PLT) yield, collection efficiency (CE), leukocyte (WBC) content, and citrate usage. Below is a summary of the key findings and conclusions:

Key Findings:

1) Separation Time and Blood Volume Processed:

- The **COM.TEC** required significantly more blood (3,497 mL) to reach a target platelet yield of 3.3×10^{11}, compared to the **Amicus** (2,866 mL, $p < 0.001$). •The **COM.TEC** also had a significantly longer separation time (63 minutes) compared to the **Amicus** (47 minutes, $p < 0.001$). This difference aligns with prior studies, where the COM.TEC was found to require more time for platelet collection [17, 18].

2) Platelet Yield:

- **PLT yield per component** was similar between the devices, with no significant difference (3.39×10^{11} for Amicus vs. 3.33×10^{11} for COM.TEC, $p = 0.185$). •However, the **Amicus** showed a higher **yield per blood volume processed** (0.42) compared to the **COM.TEC** (0.33, $p < 0.001$), indicating that the **Amicus** is more efficient in collecting platelets from the same amount of blood.

3) Leukocyte Reduction:

- Both instruments consistently achieved leukoreduction, with all products meeting the **<5 × 10⁶ WBC** threshold.
- There was no significant difference in **WBC content** between the two instruments, with **Amicus** showing **94% of products** with <1 × 10⁶ WBC, and **COM.TEC** showing **87%** ($p = 0.325$).

4) Citrate Usage and Adverse Reactions:

- The **COM.TEC** required more **ACD (anticoagulant)** (373 mL) compared to the **Amicus** (300 mL, $p < 0.001$).
- Despite the higher ACD consumption, the **citrate load per minute** was slightly lower for the **COM.TEC** (6.1 ± 0.5 ml/min) than the **Amicus** (6.6 ± 0.8 ml/min, $p = 0.042$).
- **Citrate-related mild toxicity** was observed more frequently with the **COM.TEC** (42 donors) than with the **Amicus** (34 donors), although these reactions were mild and clinically insignificant

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