Original article

A comparative study of platelet loss during stem cell collection using automated blood cell separators

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Abstract:

Introduction: *Hematopoietic stem cell transplantation (HSCT) is one of the standard treatments for hematologic malignancies. Automated blood cell separators are used to collect hematopoietic stem cells from peripheral blood. However, platelet loss remains a challenge.* ***Objective:*** *This study aims to compare the rate of platelet loss between two automated blood cell separators, COM.TEC and Amicus, in patients undergoing autologous peripheral blood stem cell collection (PBSC), in order to provide recommendations for device selection in patients with thrombocytopenia or those with high bleeding risk.* ***Materials and Methods:*** *This is a retrospective study in 60 hematologic malignancy patients requiring autologous PBSC, pre-leukapheresis and post-leukapheresis patients' data were analyzed.* ***Results:*** *Each device was used in 30 patients. The median platelet count (Q1-Q3) in patients using Amicus was 95 (83-127) $x10^3$/μL before collection and 85 (65-110) $x10^3$/μL after collection, resulting in a platelet loss of 14.0 (3.5-20.7) %. In patients using COM.TEC, the median platelet count was 87 (67-108) $x10^3$/μL before collection and 64 (50-85) $x10^3$/μL after collection, resulting in a platelet loss of 26.5 (19.3-29.6) %. There was a statistically significant difference in platelet loss between the two blood cell separators at $p < 0.05$. No significant complications were observed in either device.* ***Conclusion:*** *The platelet loss rate was statistically lower in those using Amicus compared to COM.TEC. No severe complications were observed. Therefore, Amicus device may be recommended over COM.TEC device for PBSC in patients with low pre-apheresis platelet counts or those at risk of thrombocytopenia.*

Keywords : ● *Platelet loss* ● *Automated blood cell separator* ● *Autologous peripheral blood stem cell collection*

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นิพนธ์ต้นฉบับ

การศึกษาเปรียบเทียบอัตราการสูญเสียเกล็ดเลือดระหว่างเก็บเซลล์ต้นกำเนิดด้วยเครื่องแยกส่วนประกอบโลหิตแบบอัตโนมัติ

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บทคัดย่อ

บทนำ *การปลูกถ่ายเซลล์ต้นกำเนิด เป็นหนึ่งในการรักษามาตรฐานสำหรับมะเร็งทางโลหิตวิทยา โดยเครื่องปั่นแยกส่วนประกอบโลหิตอัตโนมัติถูกนำมาใช้สำหรับเก็บเซลล์ต้นกำเนิดจากกระแสเลือด อย่างไรก็ตาม การสูญเสียเกล็ดเลือดยังคงเป็นปัจจัยสำคัญ* ***วัตถุประสงค์*** *การศึกษานี้มีวัตถุประสงค์เพื่อเปรียบเทียบอัตราการสูญเสียเกล็ดเลือดระหว่างเครื่องแยกเซลล์อัตโนมัติสองรุ่น (Amicus และ COM.TEC) ในการเก็บเซลล์ต้นกำเนิด เพื่อให้คำแนะนำสำหรับการเลือกใช้เครื่องมือในผู้ป่วยที่มีภาวะเกล็ดเลือดต่ำหรือมีความเสี่ยงสูงต่อภาวะเลือดออกผิดปกติ* ***วัสดุและวิธีการ*** *เป็นการวิจัยย้อนหลังในผู้ป่วยโรคมะเร็งทางโลหิตวิทยาจำนวน 60 รายที่ต้องการการเก็บเซลล์ต้นกำเนิดจากร่างกายตัวเอง โดยใช้เครื่องแยกเซลล์เม็ดเลือดสองชนิด แล้วจึงวิเคราะห์ข้อมูลปริมาณเกล็ดเลือดของผู้ป่วยก่อนและหลังการเก็บเซลล์ต้นกำเนิด* ***ผลการศึกษา*** *เครื่องปั่นแยกส่วนประกอบโลหิตแต่ละเครื่องถูกใช้ในการเก็บเซลล์จากผู้ป่วยจำนวนเครื่องละ 30 ราย ค่ามัธยฐาน (ควอร์ไทล์ที่1-ควอร์ไทล์ที่3) ของปริมาณเกล็ดเลือด ในผู้ป่วยที่ใช้เครื่อง Amicus คือ 95 (83-127) $x10^3/\mu L$ ก่อนการเก็บเซลล์ต้นกำเนิด และ 85 (65-110) $x10^3/\mu L$ หลังการเก็บเซลล์ต้นกำเนิด ดังนั้นจึงมีการสูญเสียเกล็ดเลือด 14.0 (3.5-20.7) % สำหรับผู้ป่วยที่ใช้เครื่อง COM.TEC คือ 87 (67-108) $x10^3/\mu L$ ก่อนการเก็บเซลล์ต้นกำเนิด และ 64 (50-85) $x10^3/\mu L$ หลังการเก็บเซลล์ต้นกำเนิด ส่งผลให้มีการสูญเสียเกล็ดเลือด 26.5 (19.3-29.6) % โดยมีความแตกต่างอย่างมีนัยสำคัญของการสูญเสียเกล็ดเลือดระหว่างเครื่องแยกเซลล์เม็ดเลือดสองชนิด ที่ $p < 0.05$ ไม่พบภาวะแทรกซ้อนทางคลินิกที่มีนัยสำคัญระหว่างการเก็บเซลล์ต้นกำเนิดด้วยเครื่องทั้งสองชนิด* ***สรุป*** *อัตราการสูญเสียเกล็ดเลือดต่ำกว่าอย่างมีนัยสำคัญทางสถิติในผู้ป่วยที่ใช้เครื่อง Amicus เมื่อเทียบกับเครื่อง COM.TEC โดยไม่พบภาวะแทรกซ้อนรุนแรงระหว่างการเก็บเซลล์ต้นกำเนิด ดังนั้นในผู้ป่วยที่มีจำนวนเกล็ดเลือดต่ำหรือผู้ที่มีความเสี่ยงต่อภาวะเกล็ดเลือดต่ำควรเก็บเซลล์ต้นกำเนิดด้วยเครื่อง Amicus เพื่อลดอัตราการสูญเสียเกล็ดเลือด*

คำสำคัญ : ● *อัตราการสูญเสียเกล็ดเลือด* ● *เครื่องปั่นแยกส่วนประกอบโลหิตแบบอัตโนมัติ*
● *การเก็บเซลล์ต้นกำเนิดจากกระแสเลือดจากร่างกายตนเอง*

วารสารโลหิตวิทยาและเวชศาสตร์บริการโลหิต. 2568;35:249-55.

Introduction

Hematopoietic stem cell transplantation (HSCT) could provide a potentially curative treatment for many patients with hematologic malignancies.[1] This treatment has evolved significantly since the 1950s and has become one of the standard therapies nowadays.[2] Hematopoietic stem cell collection is a crucial step for the success of the treatment.[2,3] Stem cells can be collected directly from the bone marrow, a painful procedure associated with risks of anesthesia.[3] Peripheral blood stem cell collection (PBSC) using automated blood cell separators was developed, significantly reducing patient discomfort and risks.[2,3] However, this method still poses challenges, particularly its impact on other blood components, especially platelets.[4,11]

Patients with hematologic malignancies are already at risk of thrombocytopenia due to the disease itself and chemotherapy.[4,11,14] Additional platelet loss during stem cell collection may increase the risk of bleeding and compromise patient safety.[14] Automated blood cell separators have been continuously improved to enhance stem cell collection efficiency and minimize adverse effects.[5,6] Fresenius-Kabi COM.TEC device is widely used in many institutions[5], while Fresenius-Kabi Amicus separator represents newer technology with higher precision.[9] Previous study showed lower rate of apheresis-induced thrombocytopenia in patients using Amicus compared with other devices[4], but data in Thailand remains limited. Economic factors are also important in selecting the appropriate device[13], as HSCT is a costly treatment. Reducing complications and need for platelet transfusions is crucial for both clinical outcomes and cost-effectiveness.[11,14] Therefore, this study focuses on comparing platelet loss between the COM.TEC and Amicus in patients undergoing autologous PBSC to contribute to the limited comparative data available in Thailand regarding apheresis technology performance, ultimately supporting cost-effective and clinically optimal decision-making in hematopoietic stem cell transplantation programs. The primary objective was to quantify and analyze the differences in platelet depletion between these two widely used apheresis devices, in order to determine which technology better preserves platelet during the collection process. Additionally, this research sought to evaluate whether the technological differences between the newer Amicus system, with higher precision capabilities, and the more established COM.TEC device translate into clinically significant outcomes regarding platelet preservation. By assessing these differences, the study intended to provide evidence-based recommendations for device selection in patients with pre-existing thrombocytopenia or those at high risk of bleeding complications. Furthermore, this investigation aimed to contribute to the limited comparative data available in Thailand regarding apheresis technology performance, ultimately supporting cost-effective and clinically optimal decision-making in hematopoietic stem cell transplantation programs.

Materials and Methods

Patients

This retrospective study was conducted from January 2024 to December 2024 at a tertiary care hospital, with approval from the Ethics Committee, Faculty of Medicine, Chulalongkorn University (IRB No.0374/67). Sixty patients with hematologic malignancies undergoing autologous PBSC were included in the study and divided equally into two groups: the first group using Amicus device and the other using COM.TEC device. The patients were pre-evaluated with complete blood count (CBC) and pre-CD34+ cell counts. Vascular access was established and the central line was used in all patients. Vital signs were monitored throughout the procedure. Signs of citrate toxicity and other complications[10] were observed. After the procedure, CBC was re-evaluated.

The blood cell separators

Amicus cell separator Version 5.13 (Fresenius-Kabi HemoCare GmbH, Bad Homburg, Germany) and COM.TEC cell separator Version 4.03.08 (Fresenius-Kabi HemoCare GmbH, Bad Homburg, Germany) used in apheresis

procedures. They are advanced medical device used to separate and collect specific blood components, such as platelets, plasma or white blood cells, from a donor or patient. These machines operate using continuous-flow centrifugation technology, which separates blood components based on their density. The processing volumes were 2-3 times the total blood volume. Anticoagulant (acid citrate dextrose solution A, ACD-A): whole blood ratios were 1:12 to 1:14. The whole blood flow rate was 50-60 mL/min adjusted based on patient weight and hematocrit.

Statistical analysis

Continuous variables were described by median (IQR) or mean ± standard deviation (SD) where appropriate. Since the data has a non-parametric distribution, the mean and median are significantly different. In addition, the distribution is not bell-shaped and the data is asymmetrical. Therefore, Mann-Whitney U test was used for comparison. This study compared platelet loss rates between the two groups using Mann-Whitney U test in GraphPad Prism Software Version 9 (Dotmatics, MA, USA), with a statistical significance level set at $p < 0.001$.

Results

Patient characteristics

A total of 60 patients underwent autologous stem cell collection using two different apheresis devices: 30 patients with the Amicus device and 30 patients with the COM.TEC device. Of 30 patients using Amicus device, multiple myeloma (MM) was the most common diagnosis, which included 12 cases (40.0%), followed by 6 cases (20.0%) of diffuse Large B-Cell Lymphoma (DLBCL); 3 cases (10.0%) of peripheral T-Cell Lymphoma (PTCL); 3 cases (10.0%) of lymphoma not otherwise specified; 2 cases (6.7%) of follicular Lymphoma (FL); 2 cases (6.7%) of relapsed/refractory classic Hodgkin lymphoma (HL); 1 case (3.3%) of mantle cell lymphoma (MCL); and 1 case (3.3%) anaplastic large cell lymphoma (ALCL).

Of the other group with COM.TEC cell separator, multiple myeloma (MM) was the predominant diagnosis (10 cases, 33.3%), followed by 8 cases (26.7%) of mantle cell lymphoma (MCL); 8 cases (26.7%) of DLBCL; 2 cases (6.7%) of primary mediastinal B-cell lymphoma (PMBCL); 1 case (3.3%) of primary CNS lymphoma; and 1 case (3.3%) of Leukemia.

Both groups demonstrated comparable baseline hematological parameters and pre-procedure laboratory values. In Amicus device group (n = 30), demographic analysis revealed a predominance of male participants (60.0%, n = 18) compared to females (40.0%, n = 12). The mean body weight was 62.2 ± 18.6 kg, with a wide range from 39.3 to 117.0 kg. Pre-procedure laboratory parameters demonstrated considerable variability in hematological parameters. The median white blood cell count (Q1-Q3) was 22.3 $x10^3$/μL (14.4-40.0), while the median hematocrit was 29.2% (27.3-31.3). Regarding stem cell mobilization markers, the median CD34+ percentage was 0.09% (0.05-0.16), corresponding to a median absolute CD34+ count was 21.9/μL (7.1-41.8) (Table 1).

In the COM.TEC device group (n = 30), demographic analysis revealed a predominance of male participants (70.0%, n = 21) compared to females (30.0%, n = 9). The mean body weight was 67.5 ± 12.3 kg, with a wide range from 47.8 to 91.6 kg. Pre-procedure laboratory parameters demonstrated considerable variability in hematological parameters. The median white blood cell count (Q1-Q3) was 12.8 $x10^3$/μL (9.1-24.9), while the median hematocrit was 29.8% (25.7-32.9). Regarding stem cell mobilization markers, the median CD34+ percentage was 0.16% (0.07-0.37), corresponding to a median absolute CD34+ count of 27.5/μL (12.7-50.2) (Table 1).

The percentage of platelet loss during PBSC collection

In Amicus™ group, the median (Q1-Q3) pre-collection platelet count was 95 $x10^3$/μL (83-127), which decreased to a median (Q1-Q3) post-collection value of 85 $x10^3$/μL (65-110), representing a statistically significant reduction ($p < 0.05$). This calculated median (Q1-Q3) platelet loss was 14.0% (3.5-20.7).

Table 1 Baseline patient characteristics: Amicus vs COM.TEC

Characteristics	Amicus (n = 30)	COM.TEC (n = 30)	*p*-value
Demographics			
Gender, n (%)			
Male	18 (60.0)	21 (70.0)	
Female	12 (40.0)	9 (30.0)	
Weight (kg), mean (range)	62.2 (39.3-117.0)	67.5 (47.8-91.6)	
Pre-procedure laboratory values, median (Q1-Q3)			
White blood cell count (x10^3/μL)	22.3 (14.4-40.0)	12.8 (9.1-24.9)	< 0.05
Platelet pre count (x10^3/μL)	95 (83-127)	87 (67-108)	< 0.05
Hematocrit (%)	29.2 (27.3-31.3)	29.8 (25.7-32.9)	0.7007
CD34+ (%)	0.09 (0.05-0.16)	0.16 (0.07-0.37)	0.1008
CD34+ count (cells/μL)	21.9 (7.1-41.8)	27.5 (12.7-50.2)	0.5011

Table 2 Comparison of platelet loss between Amicus and COM.TEC Devices (n = 60)

Device	Number of samples (N)	Platelet count before collection (x10^3/μL)	Platelet count after collection (x10^3/μL)	Platelet loss (%)
Amicus	30	95 (83-127) Median (Q1-Q3)	85 (65-110) Median (Q1-Q3)	14.0 (3.5-20.7) Median (Q1-Q3)
COM.TEC	30	87 (67-108) Median (Q1-Q3) $p < 0.05$	64 (50-85) Median (Q1-Q3) $p < 0.05$	26.5 (19.3-29.6) Median (Q1-Q3) $p < 0.05$

Table 3 Comparison of Product Between Amicus and COM.TEC Devices (n = 60)

Parameter	Amicus Median (Q1-Q3)	COM.TEC Median (Q1-Q3)	*p*-value
Produce volume (ml)	180 (128-213)	357 (270-427)	< 0.05
CD34+ yield (x10^6 cells)	107.5 (30.5-175.8)	105.8 (60.4-345.2)	0.4420
HCT in product (%)	4.3 (3.4-5.6)	6.6 (4.6-7.2)	< 0.001
Platelet count in product (x10^3/μL)	327 (213-482)	1,421 (1,038-1,740)	< 0.001

For patients in COM.TEC group, the median (Q1-Q3) pre-collection platelet count of 87 x10^3/μL (67-108), which decreased to a median (Q1-Q3) post-collection value of 64 x10^3/μL (50-85), also representing a statistically significant decrease ($p < 0.05$). The calculated median (Q1-Q3) platelet loss was 26.5% (19.3-29.6) (Table 2).

The percentage of platelet loss between Amicus™ and COM.TEC devices during autologous PBSC collection was significantly different (14.0% vs. 26.5%, $p < 0.05$). No severe complications were observed during PBSC collection with either devices.

Discussion

This study demonstrated a statistically significant difference in platelet loss between Amicus and COM.TEC devices during autologous PBSC collection, with Amicus device exhibiting markedly lower platelet loss (14.0% vs. 26.5%, $p < 0.05$). This observation carries substantial clinical implications, particularly for patients with hematologic malignancies who are already at high risk of thrombocytopenia due to their underlying disease and prior chemotherapy.[4,11,14] Amicus device has a low rate of platelet loss during PBSC collection, which may

translate into tangible benefits, including a decreased need for platelet transfusions and a lower risk of bleeding complications, thereby improving overall patient outcomes. These results align with previous studies highlighting Amicus system's advanced technology,[9] which incorporates precise optical monitoring and automated interface detection to minimize unnecessary platelet removal during PBSC collection. On the contrary, the COM.TEC device, while still effective, relies more heavily on operator-dependent adjustments,[12] which may contribute to its higher observed platelet loss. This distinction is particularly relevant in some clinical settings, such as patients requiring multiple apheresis sessions or patients with borderline platelet counts at baseline.[11,14]

Beyond the immediate clinical implications, the superior performance of Amicus device also raises important considerations regarding cost-effectiveness and resource utilization.[13] While the initial acquisition cost of Amicus system may be higher, its ability to reduce platelet loss could lead to downstream savings by decreasing transfusion requirements and associated complications. This is especially pertinent in resource-limited settings where blood products are scarce or expensive. However, it is important to acknowledge that COM.TEC device remains a viable option in many institutions, particularly those with extensive experience using this system.[5] COM.TEC's flexibility and operator-controlled interface adjustments may offer advantages in specific scenarios, such as when collecting stem cells from patients with unusual cell distributions or when tailoring collections to specific clinical needs.[12,15]

The study's retrospective design and relatively small sample size represent some limitations that warrant caution in generalizing these findings. The heterogeneous patient population, encompassing various hematologic malignancies, may also introduce confounding variables that were not fully accounted for in the analysis. For instance, differences in disease biology, prior treatments, or mobilization regimens[3] could influence platelet dynamics independently of the apheresis device used. Future prospective studies with larger, more homogeneous cohorts would be valuable to validate these results and explore potential subgroup differences. Additionally, further research could investigate whether the observed reduction in platelet loss with the Amicus device correlates with measurable improvements in clinical endpoints, such as bleeding rates or transfusion-free survival.[14]

Another area worthy of exploration is the learning curve associated with each device.[12] While the Amicus system's automation may reduce variability, it also requires specialized training to optimize its use. In contrast, the COM.TEC's manual controls, though potentially more prone to operator error, may allow experienced teams to achieve comparable outcomes through meticulous adjustment.[7,15] Institutional factors, such as staff expertise and procedural volume, may play a critical role in determining which device is more suitable for a given setting. This emphasized the importance of individualized decision-making, where device selection is tailored to both patient characteristics and local operational realities.

This study adds to the evidence supporting the Amicus device as a superior option for minimizing platelet loss during PBSC collection.[9] The clinical benefits of reduced platelet loss, including fewer transfusions and enhanced patient safety, particularly for high-risk patients, which make Amicus an attractive choice.[11,14] However, COM.TEC device remains a reliable alternative, especially in centers with well-established protocols and skilled operators.[5,15] As HSCT continues to evolve, ongoing technological advancements and rigorous comparative studies will be essential to optimize apheresis practices and improve outcomes for patients with hematologic malignancies.[1,2]

Conclusion

The comparison between Amicus and COM.TEC devices[5,9] in patients undergoing autologous bone marrow transplantation for various hematologic malignancies re-

vealed a significant difference in platelet loss.[4,13] Amicus device demonstrated a lower platelet loss rate (14.0% vs. 26.5%, $p < 0.05$). No severe complications were observed during stem cell collection with either devices. Therefore, Amicus device may be recom-mended over COM.TEC for stem cell collection in patients with low pre-collection platelet counts or those at risk of thrombocytopenia. COM.TEC device may be considered in cases requiring operational flexibility[8,14], as it allows manual control and customization of the collection process, enabling precise selection of cell layers based on operator requirements.[12,13,15]

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