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Review

Efficiency of autologous stem cell collection: Comparison of three different cell separators

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ABSTRACT

Peripheral blood progenitor cells (PBPC) infusion allows rapid haematological recovery after high dose chemotherapy. Efficient PBPC collection is therefore essential as rescue therapy for transplantation. In order to validate a new equipment (ComTec®, Fresenius Kabi), we compared the efficiency of three cell separators for PBPC collection in patients with haematological malignant diseases. From June 2014 to December 2015, 83 PBPC were collected in 48 patients. Three aphaeresis machines were used: Cobe Spectra® (Terumo BCT, 11), Amicus® (Fenwall, 30), and ComTec® (Fresenius Kabi, 42). The median collection efficiency was similar between the three separators. The evaluation of cell contamination in the final product revealed a lower red cell contamination with Spectra® and ComTec®, whereas the platelet contamination was lower with Amicus®. The new equipment has been validated and can be further used in routine, with a total running cost that turned out to be quite lower. Each separator has its own characteristics and advantages. Further study is needed to suggest that the choice of separator could be guided following the patient's blood characteristics.

Contents

1. Introduction

Autologous haematopoietic stem cell transplantation (HSCT) is widely used as a therapeutic option to restore haematopoiesis and reconstitute immunity after high-dose chemotherapy, in a variety of haematological disorders [1,2], mainly multiple myeloma and relapsed of refractory non-Hodgkin's lymphoma in adult patients [3]. Peripheral blood stem cells (PBSC) collected by leukaphaeresis after mobilization regimen with GCSF alone or in combination with chemotherapy [4] are the most common source of haematopoietic progenitor cells for transplantation [5].

The quality of the PBSC product, particularly the number and the viability of haematopoietic progenitor cells (CD34+ cells) is a crucial surrogate for predicting successful engraftment [6,7]. On the other hand, contaminating cells such as granulocytes in the

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Table 1
Number and diagnosis of the patients following the three protocols. (MM: Multiple Myeloma, NHL: Non Hodgkin's Lymphoma, HL: Hodgkin's Lymphoma, AML: Acute Myeloblastic Leukaemia).

	COBE Spectra (Terumo BCT)	Amicus (Fenwall)	ComTec (Fresenius Kabi)
Number of patients	8	25	31
Patient's diagnosis	MM: 6 NHL: 1 HL: 1	MM: 10 NHL: 8 HL: 2 AML: 5	MM: 9 NHL: 15 HL: 2 AML: 5
Total number of collections	11	30	42

collected graft can provoke adverse events in the recipients during or after reinfusion [8–10]. Finally, some adverse events, such as vasovagal reactions, thromboembolism or hypocalcaemia linked to the anticoagulant (citrate) use can be observed during the apheresis procedure [11,12]. Therefore, efficient and safe procedures of autologous PBSC collection are critical for the patients [13].

The cell separators and programs used for PBSC collection have been gradually improved since more than thirty years and several studies have reported measures of benchmarking and quality control in order to ensure consistent collection performance [14–18]. Since Terumo BCT decided to cease to provide support in the European market for the most commonly used cell separator, the COBE Spectra Apheresis System®, the collection centres that used it were obliged to switch to another system.

Our hospital is a tertiary referral centre for haematological diseases, JACIE accredited for autologous and related allogeneic adult HSCT. Between 2003 and 2015, 513 PBSC transplantations (377 autologous and 135 allogeneic) have been performed. In June 2014, a new device (ComTec®, Fresenius Kabi) has been bought in order to progressively replace the COBE Spectra Apheresis System®. The objective of this prospective study is to assess the performance of the mononuclear cell aphaeresis protocol on the ComTec® device (Fresenius Kabi) for collecting autologous PBSC in adult patients and to compare it to the Amicus® device (Fenwall) and Cobe Spectra Apheresis System® (Terumo BCT) in terms of collection efficiency, product cell composition and donors platelet and haemoglobin (Hb) losses.

2. Material and methods

2.1. Patient selection

From June 2014 to December 2015, we performed 83 PBSC collections in 48 consecutively eligible patients for autologous HSCT, 30 males and 18 females. The median age was 60 years (25–68). The Main diagnoses were multiple myeloma (MM, n = 16), non Hodgkin's lymphoma (NHL, n = 20), Hodgkin's lymphoma (HL, n = 4) and acute myeloblastic leukaemia (AML, n = 8). All patients received G-CSF 10 μg/kg daily for at least five days prior to mobilization, just after a chemotherapy course in the AML patients.

2.2. Aphaeresis procedure

Three different devices were used as described in Table 1. The blood volume processed was twice the total blood volume of the patient whatever the device used. The ratio anticoagulant/blood was identical in all procedures (1/12). A threshold of minimum 10 CD34+ cells per microliter was required before collection. The total CD34+ cell number targeted was adapted following the patient's treatment scheme (2×10^6 CD34 positive cells per kg per transplantation). One single procedure was sufficient in 22 patients, while in 18, 7 and 1 patient, two, three or four procedures were respectively needed.

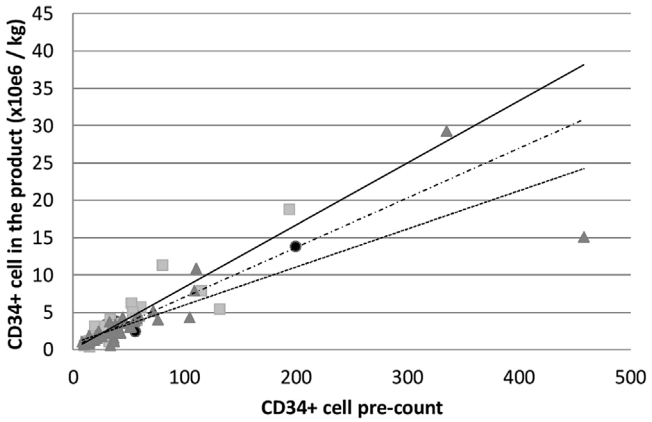

Fig. 1. Correlation between the CD34+ cell pre-count and the total CD34+ cell in the final product expressed as $n \times 10^6$ per kg body weight of the patient. The three devices as presented as follows: COBE Spectra (black circle, tendency curve ——), Amicus (grey square, tendency curve - - - -), ComTec (grey triangle, tendency curve .....).

2.3. Collection efficiency and performance variables

The collection efficiency was calculated as ratio between the total CD34+ cells collected and the circulating CD34+ cell pre-count x total blood volume processed.

The loss of patient's haemoglobin was calculated as following ratio: (Hb pre-collection – Hb post-collection)/Hb pre-collection. A similar calculation was used for the platelet loss.

2.4. Statistical analysis

Statistics were run using Excel software (Microsoft Corporation) and the XLStatistics add-on module. As most of the data were not normally distributed, results were reported as median (interquartile range). Comparisons between groups were performed using unpaired Student's *t*-tests and linear regressions when appropriate. Statistical significance was defined as $p < 0{,}05$.

3. Results

All results are shown in Table 2. CD 34 threshold (10 CD34+ cell per microliter) was obtained in all patients before collection. The CD34+ cell pre-count was not statistically different between all groups. The pre-collection patient's leucocytosis, platelet count and haemoglobin level were comparable between all groups (data not shown). The flow rate was significantly lower ($p < 0{,}001$) using the Amicus device than with the other ones. Not surprisingly the total duration of the procedure was significantly longer with this device ($p < 0{,}0001$). As the volume of anticoagulant was similar between all groups, the were no differences in frequency of adverse events during collection.

Even if slightly higher with the COBE Spectra, the collection efficiency was not statistically different between the three devices and the proportion of procedures leading to a quantitatively adequate product was higher than 50% with all protocols. No difference in terms of collection efficiency was observed between males and females. Correlation between the CD34+ cell pre-count and the total CD34+ cells in the product (Fig. 1) was heterogeneous between the three devices (COBE Spectra: R^2 0,96, $y = 0{,}0664x + 0{,}426$–Amicus: R^2 0,82, $y = 0{,}0831x + 0{,}0388$–ComTec: R^2 0,74, $y = 0{,}051x + 0{,}8909$).