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Just-in-time rescue plerixafor in combination with chemotherapy and granulocyte-colony stimulating factor for peripheral blood progenitor cell mobilization

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Abstract

Plerixafor, a recently approved peripheral blood progenitor cell mobilizing agent, is often added to granulocyte-colony stimulating factor (G-CSF) to mobilize peripheral blood progenitor cells in patients with lymphoma or myeloma who cannot mobilize enough CD34+ cells with G-CSF alone to undergo autologous stem cell transplantation. However, data are lacking regarding the feasibility and efficacy of just-in-time plerixafor in combination with chemotherapy and G-CSF. We reviewed the peripheral blood stem cell collection data of 38 consecutive patients with lymphoma (Hodgkin's and non-Hodgkin's) and multiple myeloma who underwent chemomobilization and high-dose G-CSF and just-in-time plerixafor to evaluate the efficacy of this treatment combination. All patients with multiple myeloma and all but 1 patient with lymphoma collected the minimum required number of CD34+ cells to proceed with autologous stem cell transplantation (>2 × 10^6/kilogram of body weight). The median CD34+ cell dose collected in patients with non-Hodgkin lymphoma was 4.93 × 10^6/kilogram of body weight. The median CD34+ cell dose collected for patients with multiple myeloma was 8.81 × 10^6/kilogram of body weight. Plerixafor was well tolerated; no grade 2 or higher non- hematologic toxic effects were observed.

Keywords

Just-in-time plerixafor; chemomobilization

Introduction

High-dose chemotherapy with autologous stem cell transplantation (ASCT) is considered standard therapy in patients with multiple myeloma (MM)[1–6] and relapsed chemosensitive Hodgkin lymphoma (HL) or non-Hodgkin lymphoma (NHL).[7–9] Adequate collection of peripheral blood progenitor cells (PBPC) is the first step toward successful ASCT. Unfortunately, the minimum number of stem cells needed for successful engraftment cannot be collected in approximately 5–40% of patients.[10–12] A minimum of 2.0 × 10^6 CD34+ cells per kilogram of body weight is generally considered a sufficient dose for successful ASCT, although a dose of ≥5.0 × 10^6 CD34+ cells per kilogram of body weight is associated with

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reduced time to neutrophil and platelet engraftment, duration of hospital stay, and need for blood product support.[13–16]

Peripheral blood progenitor cells are mobilized with the cytokine granulocyte-colony stimulating factor (G-CSF) filgrastim, either in steady state or following chemotherapy. Plerixafor, a novel CXCR4 inhibitor that has been approved by the Food and Drug Administration (FDA), is an effective agent for the mobilization of peripheral blood progenitor cells when used in conjunction with G-CSF.[17,18] Plerixafor inhibits the binding of stromal cell-derived factor 1 alpha to the chemokine receptor CXCR4, which causes CD34+ cells to shift from the bone marrow into the peripheral blood, allowing for optimal harvest of CD34+ cells during ASCT.[19] Published phase III studies of plerixafor in patients with lymphoma or MM demonstrated that treatment with the combination of G-CSF and plerixafor resulted in a significant increase in the CD34+ cell yield compared with treatment with G-CSF alone.[17,18,20] In addition, more patients treated with the combination of plerixafor and G-CSF than patients treated with G-CSF alone were able to proceed with ASCT and achieve successful and rapid durable neutrophil and platelet engraftment.[20]

Plerixafor has been useful in mobilizing peripheral blood progenitor cells in patients with lymphoma or MM who have been identified as poor mobilizers. The definition of a poor mobilizer varies among institutions. At our institution, we consider patients poor mobilizers when the number of circulating CD34+ cells in the peripheral blood is less than 10×10^9 per liter of blood or when at least 0.3×10^6 CD34+ cells per kilogram of body weight cannot be collected in 2 consecutive attempts. However, there is insufficient data in the literature on the safety and efficacy of just-in-time plerixafor with chemotherapy and G-CSF in patients who are considered poor mobilizers.[21–23] In this study, we sought to evaluate the feasibility and efficacy of this approach in our patient population who were deemed high risk for mobilization failure based on PB CD34+ counts of $<10 \times 10^9$/L or low yield of collected CD34+ cells

Patients and Methods

Patients

This study was approved by the Institutional Review Board of The University of Texas MD Anderson Cancer Center. We retrospectively reviewed peripheral blood stem cell collection data of 38 consecutive patients with NHL, HL, or MM at The University of Texas M.D. Anderson Cancer Center between January 1, 2009, and March 18, 2011, who underwent chemomobilization followed by treatment with high-dose G-CSF and just-in-time plerixafor. This was the first mobilization attempt at our institution for each patient.

Plerixafor

Starting in January 2009, and applying to all patients in the period studied, a risk-adapted approach to treatment with plerixafor (preemptive, or just-in-time plerixafor) in patients who were considered “poor mobilizers” was used at our institution. Specifically, plerixafor was added to G-CSF if the peripheral blood CD34+ counts plateaued at $<10 \times 10^9$/L or declined without reaching a maximum of 10×10^9/L after recovery of white blood cell counts following chemotherapy. In some cases plerixafor was added if the number of CD34+ cells collected was $<0.3 \times 10^6$ per kilogram of body weight per day for 2 consecutive days or for a progressive decline in daily collection yield. The target doses for stem cell collection at our institution were 5×10^6 CD34+ cells per kilogram of body weight for patients with NHL or HL and 8×10^6 CD34+ cells per kilogram of body weight for patients with MM (assuming the patient would undergo 2 transplants. The minimum acceptable dose to

proceed with ASCT was 2×10^6 CD34+ cells per kilogram of body weight for either lymphoma or MM.

Leukapheresis was performed using the COBE Spectra cell separator (COBE BCT, Inc., Lakewood, CO) to check circulating CD34+ cell levels and to collect CD34+ cells. Three times the estimated blood volume was processed during each collection. Anticoagulant citrate dextrose solution (ACD-A) was used. Calcium was administered via continuous infusion through the return line. The total nucleated cell count and CD34+ cell concentration were measured immediately after completion of apheresis. The CD34+ cell concentration was analyzed using 2-color flow cytometry.

Statistical Analysis

The primary endpoint of this study was the safety and efficacy of plerixafor in combination with G-CSF after chemotherapy. Secondary endpoints included the number of patients who reached the target CD34+ dose, number of leukapheresis procedures required to reach the target dose, number of plerixafor injections administered, median number of CD34+ cells (per kilogram of body weight) collected, and engraftment kinetics of patients who underwent high-dose chemotherapy and ASCT. Descriptive statistics were used to summarize and report the data.

Results

Patient Demographics

During the period studied, a total of 697 patients (MM: 443, NHL: 201, HL: 53) underwent peripheral blood stem cell mobilization. Of these patients, 95 (14%) received plerixafor; 38 patients underwent chemotherapy followed by treatment with G-CSF and plerixafor and the remaining 57 patients were treated with plerixafor and high-dose G-CSF without any other chemotherapy. Of the 38 patients who received chemotherapy plus G-CSF and plerixafor, 18 were male and 20 were female, and 27 had NHL, 9 had MM, and 3 had HL (Table 1). The median age was 61 years (range, 41–75 years).

Chemomobilization Regimens

Disease-specific chemomobilization was administered according to institutional standards of care. The most commonly used mobilization regimens for patients with NHL and HL were ifosfamide and etoposide ± rituximab (n = 15) and single-agent cyclophosphamide ± rituximab (n = 6). The most commonly used chemotherapy regimens for patients with MM were cyclophosphamide (n = 3) and modified hyperfractionated cyclophosphamide, vincristine, doxorubicin (Adriamycin), and dexamethasone ± bortezomib (mod CVAD; n = 5).

G-CSF was administered at a dose of 10 mcg/kg body weight per day (rounded to the nearest vial size) starting 24 hours after completion of the chemotherapy. In some cases, the G-CSF dose was increased to 20 mcg/kg body weight prior to the addition of plerixafor.

Plerixafor was administered at the standard dose of 0.24 mg/kg actual body weight (maximum of 40 mg), 12 ± 2 hours before leukapheresis. For patients with creatinine clearance of <50 mL/minute, the dose was reduced to 0.16 mg/kg actual body weight, up to a maximum of 27 mg. Treatment with G-CSF was continued concurrently with plerixafor until leukapheresis was complete.

Plerixafor was given to 24 patients (63%) because they were “poor mobilizers” (i.e., circulating CD34+ counts did not exceed 10×10^9/L after recovery of total white blood cell

count following chemotherapy). In 14 patients (37%), plerixafor was added midway through the collection because the target collection goal (5×10^6 CD34+ cells per kilogram of body weight or 8×10^6 CD34+ cells per kilogram of body weight) was not reached or because of poor stem cell yield during the previous leukapheresis procedure. Four of these 14 patients received plerixafor even though the CD34+ yield before the addition of plerixafor was $>2 \times 10^6$/kg body weight, at the discretion of the treating physician. One patient with NHL started collection with a circulating peripheral blood CD34+ count of 46×10^9/L but only 0.21×10^6 CD34+ cells per kilogram of body weight were collected on day 1 of collection; therefore plerixafor was administered. It is possible that the circulating peripheral blood count was a laboratory error given the poor yield. Leukapheresis was continued until the target dose, or a minimum dose of 2×10^6 CD34+ cells per kilogram of body weight, was reached.

Toxicity

Overall, 38 non-hematological adverse events felt to be possibly, probably or definitely related to plerixafor were reported (Common Terminology Criteria for Adverse Events version 4). Most events were grade 1 or 2. None of the events were classified as serious. Adverse events included diarrhea (*n*=2), nausea (*n*=5), bone/joint/back pain (*n*=10), lower extremity swelling (*n*=2), dizziness (n=1), altered sleep pattern (*n*=1) and fatigue grade 1 (*n*=17). All were grade 2 or lower.

Leukapheresis Data

Leukapheresis data are summarized in Tables 2 and 3. In all of the patients with MM and HL and 26 of the 27 patients with NHL (96%), $\geq 2 \times 10^6$ CD34+ cells per kilogram of body weight were successfully collected. The median CD34+ cell dose collected was 5.08×10^6 cells per kilogram of body weight (range, $1.95–16.55 \times 10^6$/kg body weight). In 15 patients with lymphoma (both HL and NHL; 50%), $>5 \times 10^6$ CD34+ cells per kilogram of body weight were collected. In 6 of the 8 patients with MM (75%), $>6 \times 10^6$ CD34+ cells per kilogram of body weight were collected. The median number of plerixafor injections administered per patient for the overall study population was 4 (range, 1–5) and the median number of leukapheresis procedures per patient was 5 (range, 1–10).

In patients with lymphoma (NHL plus HL; Table 3), the median CD34+ dose collected was 5.04×10^6 cells per kilogram of body weight. Patients received a median of 4 (range, 1–4) plerixafor injections and underwent a median of 5 (range, 2–10) leukapheresis procedures. The median time from the start of chemotherapy to the first dose of plerixafor was 19.5 days (range, 14–39 days).

Patients with MM (Table 3) had a higher target collection goal than patients with lymphoma; not surprisingly, the 9 patients in this group required a median of 7 (range, 5–9) leukapheresis procedures. The median dose collected was 8.81×10^6 CD34+ cells per kilogram of body weight (range, $2.86–16.55 \times 10^6$/kg body weight). Patients received a median of 4 (range, 1–4) plerixafor injections. The median time from the start of chemotherapy to the first dose of plerixafor was 20 days (range, 16–25 days).

Outcomes

Patient outcomes are summarized in Table 4. Thirty-six patients (95%) were able to proceed with ASCT. All of these patients successfully engrafted neutrophils; the median time to engraftment was 11 days (range, 9–16 days). Two patients died before successful platelet engraftment ($>20 \times 10^9$/L).

Discussion

Although several studies have examined the use of plerixafor and high-dose growth factors for stem cell mobilization, the optimal timing and indications for the use of plerixafor after chemomobilization are unclear. Since the FDA approval of plerixafor in December 2009, most institutions have developed algorithms for its use that are based on internal data. Available data suggest that myelosuppressive chemotherapy with hematopoietic growth factor support results in higher CD34+ cell yields compared with mobilization with growth factor alone, although the overall failure rates are similar.[3] Chemomobilization is generally prescribed for patients who need additional cytoreduction prior to ASCT. Alternatively, in some cases, the penultimate or final round of salvage chemotherapy is used as the mobilization chemotherapy. Our study is one of the largest single-center studies examining chemotherapy followed by treatment with high-dose G-CSF and “just-in- time” plerixafor for peripheral blood progenitor cell mobilization.[22–24]

Gopal et al recently published a study in which 26 patients were treated with plerixafor after chemotherapy, either as a planned strategy or because of factors suggesting poor stem cell yield during leukapheresis. In their study, 13% of patients required plerixafor as rescue strategy because of peripheral blood CD34+ cell concentrations $<10 \times 10^9$/L or because of low CD34+ cell yields during leukapheresis. Patients received a median of only 1 plerixafor injection (range, 1–4), which is lower than in our study, possibly because their study used a lower stem cell target dose. In 87% of the patients, at least 2×10^6 CD34+ cells per kilogram of body weight were collected, and in 67%, 4×10^6 CD34+ cells per kilogram of body weight were collected. Median collections for patients with lymphoma (n = 24) were 4.1×10^6 per kilogram of body weight, and for patients with MM (n = 15), 8.3×10^6 CD34+ cells per kilogram of body weight. In their study, a single dose of plerixafor was associated with an increase in the mean peripheral blood CD34+ concentration to 17.2 cells/μL and an increase in the mean CD34+ cell yield following a single leukapheresis procedure to 5.11×10^6/kg body weight.[24]

In another study, Awan et al examined patients who were treated with a median of 2 doses of plerixafor as salvage treatment when an adequate number of peripheral blood progenitor cells could not be mobilized after neutrophil recovery. That study showed that plerixafor use was safe in this context, and treatment with plerixafor resulted in a 2.4× increase in peripheral blood CD34+ cell counts and a 3.9× increase in total CD34+ cell yields. In all patients, $\geq 2 \times 10^6$ CD34+ cells per kilogram of body weight were collected.[21]

In a study by Attolico et al[20], 37 patients with lymphoma or MM who were predicted to be poor mobilizers underwent disease-specific chemotherapy followed by treatment with G-CSF. In that study, plerixafor was found to be safe, and no significant adverse events were recorded. Attolico et al observed that the number of circulating CD34+cells following treatment with plerixafor was 4 times (range, 1.4–32 times) higher than the baseline CD34+ cell concentration. In 27 of the 37 patients, $\geq 2 \times 10^6$ CD34+ cells per kilogram of body weight were collected in 1–3 apheresis procedures. Patients achieved rapid and durable hematologic recovery following ASCT with plerixafor-mobilized peripheral blood stem cells.

In a study by Jantunen et al,[25] plerixafor was administered to 16 patients owing to low peripheral blood CD34+ cell counts (n = 12) or poor yield during the first leukapheresis procedure (n = 4). The median number of plerixafor injections was 1 (range, 1–3). Peripheral blood CD34+ counts after plerixafor injection were 5 times higher than before the injection. A median of 2.9×10^6 (range, 1.6–6.1) CD34+ cells per kilogram of body weight were collected using a median of 1 leukapheresis procedure (range, 1–3) in 14 of 16 patients

who underwent leukapheresis. Thirteen of 16 patients treated with a combination of chemomobilization and plerixafor received high-dose therapy with stem cell support, and all patients successfully engrafted. Jantunen et al concluded that pre-emptive use of plerixafor after chemomobilization was efficient and safe and should be considered for patients who are poor mobilizers to avoid collection failure.

In our study, in all patients with MM and HL and 96% of patients with NHL, adequate stem cells were collected and the patients were able to proceed with ASCT. Randomized studies are needed to confirm that chemotherapy followed by treatment with high-dose growth factors reduces the overall rates of failure to mobilize compared with chemotherapy followed by growth factors plus "just-in-time" plerixafor. Sixty-three percent (24 of 38) of patients in our study received plerixfor because of peripheral blood CD34+ cell concentration of $<10 \times 10^9$/L. Thirty-seven percent of patients received plerixafor during leukapheresis because of failure to collect the target cell dose desired by the transplant physician. Most patients (95%) were able to proceed to transplant and all were able to engraft neutrophils, in a median of 11 days (range, 9–16 days).

Limitations of our study include its retrospective nature, small number of patients, lack of uniformity in the CD34+ target dose required for ASCT, and lack of routine measurements of peripheral blood CD34+ counts following plerixafor administration. The patients in our study underwent more apheresis sessions and required more plerixafor doses than patients in other studies reported in the literature. This may reflect higher stem cell targets in our study compared with others or an unusually heavily pretreated patient population.

We can, however, conclude that just-in-time plerixafor administration in poor mobilizers after chemotherapy and high dose G-CSF is safe and reduces the overall failure to mobilize rate to less than 2%.

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Table 1

Patient Demographics (N = 38)

	No. (%)
Median age (range)	61 years (41–75 years)
Sex	
Male	18 (47)
Female	20 (53)
Diagnosis	
Non-Hodgkin lymphoma	27 (71)
Hodgkin lymphoma	3 (8)
Multiple myeloma	8 (21)
Prior chemotherapy regimens	
HyperCVAD >4 cycles	4 (11)
Fludarabine	1 (3)
Lenolidamide	5 (13)
Median number of prior chemotherapy regimens (range)	2 (1–4)
Prior autologous stem cell transplantation	None
Prior pelvic/spinal radiation therapy	1 (3)
Chemomobilization regimens	
HyperCVAD ± rituximab ± Bortezomib	9 (24)
Ifosfamide/etoposide ± rituximab	15 (39)
Cyclophosphamide ± rituximab	9 (24)
Ifosfamide/carboplatin/etoposide ± rituximab/ofatumomab	5 (13)

Abbreviations: hyperCVAD, hyperfractionated cyclophosphamide, vincristine, doxorubicin (Adriamycin), and dexamethasone.

Table 2

Leukapheresis data for the overall study population (N = 38)

	No. (%)
White blood cell count on day of first leukapheresis procedure	22.05 $\times 10^9$/L (4.1–71.3 $\times 10^9$/L)
Median peripheral blood CD34+ count prior to first leukapheresis procedure (range)*	7.5 $\times 10^9$/L (1–46 $\times 10^9$/L)
Median no. of plerixafor injections (range)	4 (1–5)
Median no. of leukapheresis procedures (range)	5 (1–10)
Median CD34+ cells collected per kilogram of body weight (range)	5.08 $\times$ 10^6 (1.95–16.55 $\times$ 10^6)
Excluding 1 patient in whom 2 $\times$ 10^6 CD34+ cells per kilogram of body weight were collected	5.07 $\times$ 10^6 (2.34–16.55 $\times$ 10^6)
CD34+ cells collected per kilogram of body weight	
Hodgkin and non-Hodgkin lymphoma	30 (79)
<2 $\times$ 10^6	1 (3)
2–5 $\times$ 10^6	15 (50)
>5 $\times$ 10^6	15(47)
Multiple myeloma	8 (21)
<2 $\times$ 10^6	0 (0)
2–6 $\times$ 10^6	2 (25)
>6 $\times$ 10^6	6 (75)

*Not including data from one patient with non-Hodgkin lymphoma, who started leukapheresis with peripheral blood CD34+ counts of 46 $\times$ 10^9/L but only 0.21 $\times$ 10^6 CD34+ cells per kilogram of body weight were collected after the first leukapheresis procedure.

Table 3

Leukapheresis data by diagnosis

	Median (range)		
	NHL, n = 27	**MM, n = 9**	**NHL+HL, n = 30**
White blood cell count on day of first leukapheresis procedure	22.05 × 10^9/L (4.1–71.3 × 10^9/L)	18 × 10^9/L (4.8–45.6 × 10^9/L)	21.3 × 10^9/L (4.1–71.3 × 10^9/L)
Peripheral blood CD34+ count prior to first leukapheresis procedure	4.5 × 10^9/L (1–46 × 10^9/L)	16 × 10^9/L (4–46 × 10^9/L)	7.5 × 10^9/L (1–46× 10^9/L)*
No. of plerixafor injections	3 (1–5)	4 (1–4)	4 (1–5)
No. of leukapheresis procedures	5 (2–10)	7 (5–9)	5 (2–10)
CD34+ cells collected per kilogram of body weight	4.93 × 10^6 (1.95–10.89 × 10^6)	8.81 × 10^6 (2.86–16.55 × 10^6)	5.04 × 10^6 (1.95–10.89 × 10^6)

*Not including data from 1 patient with non-Hodgkin lymphoma, who started leukapheresis with peripheral blood CD34+ counts of 46 × 10^9/L but only 0.21 × 10^6 CD34+ cells per kilogram of body weight were collected during the first leukapheresis procedure.

Table 4

Outcomes for patients who were able to proceed with autologous stem cell transplantation (N = 36)

	No. (%)
Median time to absolute neutrophil count >0.5 × 10^9/L (range)	11 days (9–16 days)
Median time to platelet count >20 × 10^9/L (range)*	14.5 days (0–114 days)
Death	10 (28)
Cause of death	
Disease relapse/progression	6 (60)
Pneumonia	1 (10)
Secondary malignancy	2 (20)
Unknown	1 (10)

*Only 34 patients successfully engrafted platelets; 2 patients died prior to engraftment