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Comparison of different plerixafor-based strategies for adequate hematopoietic stem cell collection in poor mobilizers

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ABSTRACT

Objectives: The main objective of the present study was to evaluate whether the use of plerixafor in combination with granulocyte colony-stimulating factor (G-CSF) or subsequent use of isolated G-CSF and then plerixafor following disease-specific chemotherapy, and whether it would allow for adequate peripheral stem cell collection in patients.

Methods: The retrospective study evaluated 54 patients with previous mobilization failure who were administered plerixafor in 2 centers. In patients without any side effects, CD 34+ cell counts, the percentage of patients who were found eligible for autologous transplantation, the engraftment kinetics of the patients who underwent transplantation, and their overall survival results were compared between the two groups where G-CSF was used with plerixafor, or where plerixafor was used after isolated G-CSF following chemotherapy.

Results: The median age of the patients was 49 years (range: 17-70), and 64.8% (n = 35) were males. It was identified that 31 (57.4%) patients underwent mobilization treatment with isolated G-CSF and plerixafor, and 23 (42.6%) patients underwent mobilization treatment with chemotherapy plus G-CSF and plerixafor. In all patients, mean hemoglobin level (11.3 ± 1.5 g/dL vs. 9.3 ± 1.3 g/dL; $p < 0.001$) and median platelet level (129.2 $\times 10^3/\mu L$ vs. 58.4 $\times 10^3/\mu L$) were found to be higher, while febrile neutropenia rate (3.3% vs. 60.9%), the percentage of replacement patients (6.7% vs. 65.2%), and median days of G-CSF (6 vs. 9) were found to be lower on the day of plerixafor administration in the isolated G-CSF and plerixafor group compared to the chemotherapy and G-CSF and plerixafor group.

Conclusions: In conclusion, our study demonstrated that administration of plerixafor is generally safe and well-tolerated. Regardless of the underlying disease, it offers an effective alternative for patients with previous failed mobilization attempts using conventional regimens, and allows stem cell collection with fewer apheresis sessions.

Keywords: Autologous stem cell transplantation, mobilization, plerixafor

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High dose chemotherapy followed by autologous stem cell transplantation (ASCT) remains the standard of care for transplant-eligible multiple myeloma (MM) and lymphoma patients [1-3]. Peripheral blood is the globally preferred stem cell source for ASCT [4]. However, in 5 to 40% of patients, a planned ASCT cannot be performed due to failure to mobilize sufficient number of peripheral stem cells [5]. There is evidence supporting that a minimum dose of 2×10^6 CD34 + cell/kg is required for successful hematopoietic recovery and engraftment [6-9].

It has been reported that CD34+ cell dose of $\geq 5\times10^6$/kg is associated with a shorter period of hospitalization as well as reduced need for blood transfusion and antibiotic use in transplant patients [10]. Several variables to predict mobilization failure have been identified including advanced age, bone marrow involvement, number and type of previous chemotherapies (e.g. alkylating agents, fludarabine, lenalidomide), platelet count $< 100\times10^6$/L prior to apheresis, neutropenic fever during the period of mobilization, and history of radiotherapy-particularly which targets bones that generate hematopoietic cells [5, 10-13].

The two most common mobilization strategies include using granulocyte colony-stimulating factor (G-CSF) alone or G-CSF after chemotherapy. Increment in the dose of G-CSF, administration of high-volume apheresis (processing of blood at least 3 times through a single apheresis procedure), and use of plerixafor are the options to overcome mobilization failure [14-16]. For stem cell mobilization, plerixafor (AMD3100) selectively antagonizes the chemokine receptor (CXCR-4), and reverses and inhibits the interaction with the ligand stromal cell-derived factor 1-alpha (SDF-1 alpha) [17]. Development of novel strategies with plerixafor as backbone for transplant candidates who experienced mobilization failure enables the successful implementation of ASCT.

It has been demonstrated that combination of G-CSF and plerixafor in non-Hodgkin lymphoma (NHL) and MM patients leads to a significant increase in the number of CD34 cells collected compared to G-CSF alone [18, 19].

This study evaluated the outcomes of mobilization with G-CSF in combination with plerixafor and chemotherapy plus G-CSF in combination with plerixafor. In addition, median time to neutrophil and platelet engraftment, and follow-up data after ASCT were collected. This study aimed to compare the efficacy of the use of plerixafor in combination with G-CSF or use of G-CSF and plerixafor following disease-specific chemotherapy for adequate peripheral stem cell collection. Secondary endpoints included the increase in the peripheral blood CD 34+ cell count after plerixafor administration in the different patient groups, the percentage of patients achieving to pool sufficient number of stem cells for ASCT with different mobilization regimens, the engraftment kinetics of the transplanted patients and their overall survival (OS) results. Our study demonstrated that administration of plerixafor is well-tolerated. It offers an effective alternative for patients with previous failed mobilization attempts using conventional regimens.

METHODS

This single-center, retrospective study includes 54 patients from two different transplant centers (Istanbul Medipol University and Istanbul University- Istanbul Medical Faculty) who were administered plerixafor for previous mobilization failure. This study was approved by local ethics committee of Istanbul Medipol University (study number 01.06.2021: E-10840098-772.02-2487) and performed in accordance with the principles of the Declaration of Helsinki.

Study Design

Study population consisted of adult patients diagnosed with Hodgkin lymphoma (HL), 2 NHL, MM, T-Acute Lymphoblastic leukemia (T-ALL) and 1 with testis tumor between 2015-2020 years which had mobilization failure before. All patients in the examined period were examined, no case was excluded. Medical data were obtained from patient archive files and the hospital information system.

Mobilization Failure

Mobilization failure is defined as the failure to achieve a CD 34+ cell count of $< 2 \times 106$/kg after G-CSF or chemotherapy followed by G-CSF.

Dosing and Administration

Patients were administered either 5 mcg/kg G-CSF twice a day in combination with at least a single

dose of 0.24 mg/kg plerixafor 9 to 11 hours prior to the apheresis procedure, or chemotherapy plus G-CSF in combination with at least a single dose of 0.24 mg/kg plerixafor.

Statistical Analysis

Statistical evaluation was performed using the Statistical Package for Social Sciences (SPSS) for Windows 20 (IBM SPSS Inc., Chicago, IL) program. Normal distribution of data was evaluated using the Kolmogorov-Smirnov Test. Normally distributed numerical variables were indicated as mean ± standard deviation, while numerical variables not showing normal distribution were indicated as median (min-max). Categorical variables were indicated in numbers and percentages. Chi-Square, Yates Correction and Fisher's Exact Tests were used for comparison of the categorical data. Student T Test or Mann-Whitney U Test was used to compare the numeric variables between G-CSF and CT plus G-CSF groups based on the normality distribution. ANOVA Test (post-hoc: Bonferroni Test) or Kruskall Wallis H Test (post-hoc: Dunn's Test) was used to compare numerical variables based on the diagnosis groups. Although groups with a sample size of less than 5 were not included in the analysis, the relevant data distributions are shown in Tables. $P < 0.05$ (*) value was considered significant in statistical analysis.

Table 1. Clinical and demographic features of patients

Variables	HL n = 9	NHL n = 28	MM n = 14	Other n = 3	Total n = 54	*p value*
Age (years)	32 (18-60)	50.5 (20-70)	60 (41-69)	30 (30-54)	49 (18-70)	**0.001***
Gender, n (%)						
Female	4 (44.4)	10 (35.7)	5 (35.7)	-	19 (35.2)	0.924
Male	5 (55.6)	18 (64.3)	9 (64.3)	3 (100.0)	35 (64.8)	
Pre-transplant RT, n (%)						
N/A	8 (88.9)	23 (82.1)	11 (78.6)	2 (66.7)	44 (81.5)	0.999
Yes	1 (11.1)	5 (17.9)	3 (21.4)	1 (33.3)	10 (18.5)	
Number of CT lines, n (%)						
1 Line	-	6 (21.4)	3 (21.4)	2 (66.7)	11 (20.4)	0.098
2 Lines	5 (55.6)	17 (60.7)	5 (35.7)	1 (33.3)	28 (51.9)	
3 Lines	2 (22.2)	4 (14.3)	6 (42.9)	-	12 (22.2)	
4 Lines	2 (22.2)	1 (3.6)	-	-	3 (5.6)	
Previous transplantation, n (%)						
N/A	9 (100.0)	28 (100.0)	10 (71.4)	3 (100.0)	50 (92.6)	**0.004***
Yes	-	-	4 (28.6)	-	4 (7.4)	
Previous mobilization failure, n (%)						
G-CSF	7 (77.8)	15 (53.6)	8 (57.1)	1 (33.3)	31 (57.4)	0.505
CT plus G-CSF	2 (22.2)	13 (46.4)	6 (42.9)	2 (66.7)	23 (42.6)	
Cyclosphamide+etoposide	1 (11.1)	7 (25.0)	4 (28.6)	-	12 (22.2)	0.793
Cyclosphamide	-	2 (7.1)	2 (14.3)	1 (33.3)	5 (9.3)	
ICE	1 (11.1)	2 (7.1)	-	1 (33.3)	4 (7.4)	
HD MTX+ ARA-C	-	2 (7.1)	-	-	2 (3.7)	

RT = radiotherapy, CT = chemotherapy, TX = transplant, HL= Hodgkin lymphoma, NHL = Non-Hodgkin lymphoma, MM = multiple myeloma

RESULTS

Study population consisted of a total of 54 patients, including 9 (16.7%) patients diagnosed with Hodgkin lymphoma (HL), 28 (51.9%) with NHL, 14 (25.9%) with MM, 2 (11.2%) with T-Acute Lymphoblastic leukemia (T-ALL) and 1 (5.6%) with testis tumor. The median patient age was 49 years (range:17-70 years), and 64.8% (n = 35) of the patients included were males. Thirty-one (57.4%) patients underwent mobilization with G-CSF and plerixafor, and 23 (42.6%) patients with chemotherapy plus G-CSF and plerixafor. The clinical and demographic characteristics of the patients are depicted in Table 1. The median age was lower in the HL group compared to the other groups (HL: 32 years vs. NHL: 50.5 years vs. MM: 60 years; $p = 0.001$). No patients in the HL and NHL groups had previous transplant history, while 28.6% of MM patients had a history of ASCT ($p = 0.004$). Other clinical and demographic features did not differ significantly among the diagnostic groups (Table 1).

Hemoglobin (Hgb) levels, platelet, leukocyte and neutrophil counts on the day of plerixafor administration did not differ significantly among the diagnostic groups, Median number of days of G-CSF administration and the percentage of patients who were able to undergo ASCT showed no difference among the diagnostic groups (Table 2).

The rate of complete remission (CR) at 3rd month of ASCT was similar for HL and NHL patients but lower for MM patients (HL: 44.4% vs. NHL: 42.9% vs. MM: 7.1%; $p = 0.023$). Rates of partial response (PR) and progressive disease were higher in the MM patients compared to the other diagnostic groups. The rate of mortality due to infection was higher for NHL patients compared to the other diagnostic groups (HL: 11.1% vs. NHL: 21.4% vs. MM: 0%; $p = 0.023$). Previous use of lenalidomide was identified in 57.1% of MM patients (Table 3).

In the whole study group, the number of chemotherapy lines administered was higher in patients who received G-CSF and plerixafor compared to patients who received chemotherapy plus G-CSF and plerixafor ($p < 0.001$). Other clinical and demographic characteristics did not differ significantly between the groups. The comparison of the two groups with respect to clinical and demographic features in different diagnostic categories was not possible due to low sample size. Among NHL patients, the percentage of those who received 1 line of chemotherapy was higher in the chemotherapy plus G-SCF and plerixafor group compared to the G-CSF and plerixafor group, while the percentage of patients who received 2 or more lines of chemotherapy was higher in the G-CSF and plerixafor group. Among MM patients, clinical and demographic characteristics did not differ significantly for the G-CSF and plerixafor and chemotherapy plus G-CSF and plerixafor groups (Table 4).

In the whole patient cohort, mean Hgb levels (11.3 ± 1.5 1.5 g/dL vs. 9.3 ± 1.3 1.5 g/dL ; $p < 0.001$) and median platelet counts (129.2 $\times 10^3/\mu L$ vs. 58.4 $\times 10^3/\mu L$; $p < 0.001$) were higher while the rate of febrile neutropenia (3.3% vs. 60.9%; $p < 0.001$), the percentage of patients requiring transfusion support (6.7% vs. 65.2%; $p < 0.001$), median number of days of G-CSF administration (6 vs. 9; $p = 0.001$), and median CD34 + cell counts (3×10^6/kg vs. 6.8 × 106/kg; $p < 0.001$) were lower on the day of plerixafor administration in the G-CSF and plerixafor group compared to the G-CSF plus chemotherapy and plerixafor group. On the day of plerixafor administration, G-CSF and plerixafor group and G-CSF plus chemotherapy and plerixafor group showed no significant difference for the other parameters (Table 5).

G-CSF and plerixafor and chemotherapy plus G-CSF and plerixafor mobilization regimens showed no difference for median time of engraftment in the whole study cohort as well as in patients diagnosed with NHL and MM.

Of the 37 patients who underwent ASCT, 5 (13.5%), 21 (56.8%) and 9 (24.3%) and 2 (5.4%) patients were diagnosed with HL, NHL MM and other malignancies, respectively. Median age of the ASCT patients was 50 years (range: 18-70), and 67.6% (n = 25) of the ASCT patients were males. Eighteen (48.6%) patients received mobilization treatment with G-CSF and plerixafor and 19 (51.4%) patients with chemotherapy plus G-CSF and plerixafor. Clinical and demographic characteristics of the patients who underwent ASCT showed no significant difference according to the diagnostic groups.

In patients who underwent ASCT, median days to platelet engraftment (platelet count ≥ 20k) (HL:11 vs. NHL:20 vs. MM:14; $p = 0.014$) and median days to

Table 2. **Clinical findings according to Plerixafor treatment**

Variables	HL n = 9	NHL n = 28	MM n = 14	Other n = 3	Total n = 54	*p value*
Cell counts at day of plerixafor Administration						
Hgb (gr/dL)	10.3 ± 2.0	10.5 ± 1.8	10.1 ± 1.5	10.3 ± 2.7	10.4 ± 1.8	0.845
PLT ($\times 10^3/\mu L$)	99.4 (60-227)	84.5 (22-266.8)	103.6 (40-279.5)	64.3 (55-111)	96.3 (22-279.5)	0.562
WBC ($\times 10^3/\mu L$)	22.7 (7-53)	27.5 (7-98.5)	22.9 (3.6-76)	36.8 (4.7-40)	24.9 (3.6-98.5)	0.778
ANC ($\times 10^3/\mu L$)	18.3 (4.5-47)	21.3 (4-72.5)	18.9 (2.8-38.4)	26 (3.4-31.8)	19.2 (2.8-72.5)	0.656
Length of stay for mobilization (days)	12 (6-18)	13 (6-29)	16 (7-25)	35 (10-42)	14 (6-42)	0.652
Events during mobilization						
Febrile neutropenia						
No	8 (100.0)	20 (71.4)	9 (64.3)	1 (33.3)	38 (71.7)	0.163
Yes	-	8 (28.6)	5 (35.7)	2 (66.7)	15 (28.3)	
Transfusion requirement						
No	7 (77.8)	19 (67.9)	10 (71.4)	1 (33.3)	36 (67.9)	0.999
Yes	2 (25.0)	9 (32.1)	4 (28.6)	2 (66.7)	17 (32.1)	
ES, count	1 (1-1)	3 (1-5)	2 (1-3)	6 (3-9)	3 (1-9)	0.214
Platelet, count	2 (2-2)	2 (1-9)	3 (1-7)	5 (2-8)	2 (1-9)	0.932
Number of days of G-CSF used	6 (4-8)	7 (4-17)	7 (6-15)	7 (6-14)	6.5 (4-17)	0.088
Cell count, 10^6/kg	4.725 (0.2-6.8)	3.56 (0.5-7.87)	4.05 (0.8-12.4)	4.64 (3.03-8)	4 (0.2-12.4)	0.597
Autologous transplant status, n (%)						
No	4 (44.4)	7 (25.0)	5 (35.7)	1 (33.3)	17 (31.5)	0.509
Yes	5 (55.6)	21 (75.0)	9 (64.3)	2 (66.7)	37 (68.5)	

Hgb = hemoglobin, PLT = platelet, WBC = leukocyte, ANC = neutrophil, HL = Hodgkin lymphoma, NH=: Non-Hodgkin lymphoma, MM = multiple myeloma

platelet count ≥ 50k (days) (HL:16 vs. NHL:25 vs. MM:16; $p = 0.049$) were higher in NHL patients compared to the other diagnostic groups. Time to platelet engraftment did not differ significantly in the HL and MM patients ($p > 0.05$). Time to achieve neutrophil engraftment (neutrophil count ≥500) was similar for the NHL and MM patients but shorter in patients diagnosed with HL (HL:10 vs. NHL:12 vs. MM:13; $p = 0.050$), while time to achieve neutrophil engraftment count ≥ 1000 did not differ significantly among the diagnostic groups (Table 6). Two (5.4%) patients did not achieve platelet and neutrophil engraftment due to early mortality. Platelet and neutrophil engraftment failed to occur in 6 (16.2%) patients and 1 (2.7%) patient, respectively.

Response assessment at 3rd month of ASCT showed that the rate of CR was highest in HL patients, and CR rate was higher in NHL patients compared to MM patients (HL: 80% vs. NHL:57.1% vs. MM:11.1; $p = 0.002$). The PR rate was highest in MM patients, and PR rate was higher in HL patients compared to NHL patients (HL: 20% vs. NHL:9.5% vs. MM:66.7%; $p = 0.002$). Disease progression was observed only in MM patients (22.2%). Death due to infection occurred only in NHL patients (21.4%). At 3rd month of ASCT, the diagnostic groups showed no difference in OS. All HL patients were alive, while 33.3% (n = 7) of the NHL patients and 22.2% (n = 2) of the MM patients died 3 months after ASCT. History of lenalidomide administration was documentd in 55.6% of the MM patients who underwent ASCT.

Among patients who underwent ASCT, the number of chemotherapy lines administered was higher in the G-CSF and plerixafor group compared to chemotherapy plus G-CSF and plerixafor group ($p < 0.002$). Other clinical and demographic features did not differ significantly between the G-CSF and plerixafor group and the chemotherapy plus G-CSF and plerixafor group. The comparison of the two mobilization groups with respect to clinical and demographic features in different diagnostic categories was not possible due to low sample size.

In ASCT patients mobilized with G-CSF and plerixafor compared to ASCT patients mobilized with chemotherapy plus G-CSF and plerixafor, mean Hgb level (11.5 ± 1.1 g/dl vs. 9.3 ± 1.4 g/dl; $p < 0.001$), median platelet count (143 $\times 10^3/\mu L$ vs. 52 $\times 10^3/\mu L$; $p < 0.001$), median WBC count (36.8 $\times 10^3/\mu L$ vs 21.3 $\times 10^3/\mu L$; $p = 0.050$), and the percentage of patients having required ≥ 2 days of apheresis (100% vs. 52.6%; $p = 0.001$) were higher while rate of febrile neutropenia (5.6% vs. 57.9%; $p = 0.001$), the percentage of pa-

Table 3. Short-term findings after Plerixafor administration

Variables	HL n = 9	NHL n = 28	MM n = 14	Other n = 3	Total n = 54	*p value*
Response assessment after 3-months, n (%)						
CR	4 (44.4)	12 (42.9)	1 (7.1)	2 (66.7)	19 (35.2)	**0.023***
PR	1 (11.1)	2 (7.1)	6 (42.9)	-	9 (16.7)	
Progression	1 (11.1)	1 (3.6)	3 (21.4)	-	5 (9.3)	
Death due to infection	1 (11.1)	6 (21.4)	-	-	7 (13.0)	
Unknown	1 (11.1)	5 (17.9)	2 (14.3)	1 (33.3)	9 (16.7)	
Not Collected	1 (11.1)	2 (7.1)	2 (14.3)	-	5 (9.3)	
Current status						
Dead	3 (33.3)	12 (42.9)	4 (28.6)	1 (33.3)	20 (37.0)	0.679
Alive	6 (66.7)	16 (57.1)	10 (71.4)	2 (66.7)	34 (63.0)	
Number of days of stem cell collection after mobilization, n (%)	5.5 (5-16)	6 (5-21)	6.5 (5-18)	13 (6-20)	6 (5-21)	0.176
Lenalidomide, n (%)						
N/A	-	-	5 (35.7)	-	-	-
Yes	-	-	8 (57.1)	-	-	
Unknown	-	-	1 (7.1)	-	-	0.105

CR = complete response, PR = partial response, HL = Hodgkin lymphoma, NHL = Non-Hodgkin lymphoma, MM = multiple myeloma

Table 4. Distribution of clinical and demographic features in the diagnostic groups according to mobilization regimens

Variables	HL		NHL		*p value*	MM		*p value*	Other		Total		*p value*
	G-CSF n = 7	CT n = 2	G-CSF n = 15	CT n = 13		G-CSF n = 8	CT n = 6		G-CSF n = 1	CT n = 2	G-CSF n = 31	CT n = 23	
Age (years)	32 (18-42)	40.5 (21-60)	46 (20-69)	51 (41-70)	0.363	60 (41-67)	57.5 (44-69)	0.573	30	42 (30-54)	44 (18-69)	51 (21-70)	0.111
Gender, n (%)													
Female	2 (28.6)	2 (100.0)	6 (40.0)	4 (30.8)	0.910	3 (37.5)	2 (33.3)	0.999	-	-	11 (35.5)	8 (34.8)	0.999
Male	5 (71.4)	-	9 (60.0)	9 (69.2)		5 (62.5)	4 (66.7)		1 (100.0)	2 (100.0)	20 (64.5)	15 (65.2)	
Pre-transplant RT, n(%)													
N/A	6 (85.7)	2 (100.0)	13 (86.7)	10 (76.9)	0.860	7 (87.5)	4 (66.7)	0.778	1 (100.0)	1 (50.0)	27 (87.1)	17 (73.9)	0.379
Yes	1 (14.3)	-	2 (13.3)	3 (23.1)		1 (12.5)	2 (33.3)		-	1 (50.0)	4 (12.9)	6 (26.1)	
Number of CT lines, n (%)													
1 Line	-	-	-	6 (46.2)	**0.008***	-	3 (50.0)	0.116	-	2 (100.0)	-	11 (47.8)	**< 0.001***
2 Lines	4 (57.1)	1 (50.0)	12 (80.0)	5 (38.5)		4 (50.0)	1 (16.7)		1 (100.0)	-	21 (67.7)	7 (30.4)	
3 Lines	2 (28.6)	-	2 (13.3)	2 (15.4)		4 (50.0)	2 (33.3)		-	-	8 (25.8)	4 (17.4)	
4 Lines	1 (14.3)	1 (50.0)	1 (6.7)	-		-	-		-	-	2 (6.5)	1 (4.3)	
Previous TX, n (%)													
N/A	7 (100.0)	2 (100.0)	15 (100.0)	13 (100.0)	-	5 (62.5)	5 (83.3)	0.798	1 (100.0)	2 (100.0)	28 (90.3)	22 (95.7)	0.831
Yes	-	-	-	-		3 (37.5)	1 (16.7)		-	-	3 (9.7)	1 (4.3)	

RT = radiotherapy, CT = chemotherapy, TX = transplant, HL = Hodgkin lymphoma, NHL = Non-Hodgkin lymphoma, MM = multiple myeloma

tients requiring transfusions (0% vs. 57.9%; $p < 0.001$), median days of G-CSF administered (6 vs. 9; $p = 0.011$) and median count of CD34+ cells mobilized (3.7×10^6/kg vs. 6.7×10^6/kg; $p = 0.001$) were lower on the day of plerixafor administration; while other parameters did not differ significantly between G-CSF and plerixafor group compared to the chemotherapy plus G-CSF and plerixafor group.

In NHL patients who were mobilized with G-CSF and plerixafor compared to chemotherapy plus G-CSF and plerixafor, mean Hgb level (11.3 ± 1.1 g/dL vs. 9.5 ± 1.6 g/dL; $p = 0.007$) and median platelet count (136.1×10^3/µL vs. 45 ×103/µL; $p < 0.001$) and percentage of patients having required ≥ 2 days of apheresis (100% vs. 54.6%; $p = 0.008$) were higher while the percentage of patients requiring transfusions (0% vs. 54.5%; $p = 0.012$) and median count of CD34+ cells mobilized (2.8×10^6/kg vs. 6.6×10^6/kg; $p = 0.006$) were lower on the day of plerixafor administration. On the day of plerixafor administration, other parameters did not differ significantly in the G-CSF and plerixafor group compared to chemotherapy plus G-CSF and plerixafor group in the NHL patients.

In MM patients who were mobilized with G-CSF and plerixafor compared to MM patients mobilized with chemotherapy plus G-CSF and plerixafor, mean Hgb (11.3 ± 0.9 g/dL vs. 8.9 ± 1.0 g/dL; $p = 0.008$) and median platelet count (166×10^3/µL vs. 52 × 103/µL; $p = 0.016$) were higher on the day of plerixafor administration. Other parameters did not differ significantly in the G-CSF and plerixafor group compared to the chemotherapy plus G-CSF and plerixafor group for MM patients on the day of plerixafor administration.

When G-CSF and plerixafor group and chemotherapy plus G-CSF and plerixafor group were compared for engraftment findings, the whole cohort as well as NHL and MM patients showed no significant difference.

Compared to chemotherapy plus G-CSF and plerixafor, mobilization with G-CSF and plerixafor required fewer number of days of cell collection in the whole cohort as well as in NHL and MM patients (Whole cohort = G-CSF and plerixafor: 6 days vs CT plus G-CSF and plerixafor:15 days; $p < 0.001$, NHL = G-CSF and plerixafor: 6 vs CT plus G-CSF and plerixafor: 16; $p = 0.024$, MM→ G-CSF and plerixafor: 5 vs CT plus G-CSF and plerixafor: 15; $p = 0.016$). G-

Table 5. Distribution of clinical findings in the diagnostic groups according to mobilization regimens

Variables	HL		NHL		*p*	MM		*p*	Other		Total		*p*
	G-CSF n = 7	CT n = 2	G-CSF n = 15	CT n = 13		G-CSF n = 8	CT n = 6		G-CSF n = 1	CT n = 2	G-CSF n = 31	CT n = 23	
Cell counts at day of plerixafor administration													
Hgb (gr/dL)	11.1 ± 1.7	8.5 ± 1.8	11.2 ± 1.7	9.6 ± 1.5	0.013*	11.4 ± 0.8	8.9 ± 0.9	**0.001***	13.1	8.9 ± 1.7	11.3 ± 1.5	9.3 ± 1.3	< 0.001*
PLT ($\times 10^3/\mu L$)	134 (98.7-227)	62 (60-64)	129 (22-266.8)	49 (27-141)	**< 0.001***	127.5 (93-279.5)	71.5 (40-116)	**0.026***	111 (111-111)	59.7 (55-64.3)	129.2 (22-279.5)	58.4 (27-141)	**< 0.001***
WBC ($\times 10^3/\mu L$)	22.7 (7-50.2)	35.5 (18-53)	27.9 (8-98.5)	21.3 (7-70)	0.467	26.9 (20.1-76)	18.3 (3.6-32)	0.065	36.8	22.4 (4.7-40)	27.9 (7-98.5)	21 (3.6-70)	0.088
ANC ($\times 10^3/\mu L$)	18.3(4.5-45.9)	31 (15-47)	24.8 (4-72.5)	19 (4-37)	0.387	20.7 (16.9-38.4)	13.1 (2.8-29)	0.132	31.8	14.7 (3.4-26)	23.1 (4-72.5)	19 (2.8-47)	0.110
Length of stay for mobilization, days	12 (8-16)	12 (6-18)	10 (6-29)	19 (6-27)	0.142	9 (7-23)	18.5 (16-25)	0.043*	10	38.5 (35-42)	10 (6-29)	19 (6-42)	
Events during mobilization													
Febrile neutropenia													
No	6 (100.0)	2 (100.0)	14 (93.3)	6 (46.2)	**0.019***	8 (100.0)	1 (16.7)	**0.008***	1 (100.0)	-	29 (96.7)	9 (39.1)	**< 0.001***
Yes	-	-	1 (6.7)	7 (53.8)		-	5 (83.3)		-	2 (100.0)	1 (3.3)	14(60.9)	
Transfusion requirement													
Yes	5 (83.3)	1 (50.0)	14 (93.3)	5 (38.5)	**0.007***	8 (100.0)	2 (33.3)	**0.033***	1 (100.0)	-	28 (93.3)	8 (34.8)	**< 0.001***
No	1 (16.7)	1 (50.0)	1 (6.7)	8 (61.5)		-	4 (66.7)		-	2 (100.0)	2 (6.7)	15 (65.2)	
ES, count	1 (1-1)	-	2 (2-2)	3 (1-5)	0.667	-	2 (1-3)	-	-	6 (3-9)	1.5 (1-2)	3(1-9)	0.200
Platelet, count	2 (2-2)	2 (2-2)	2 (2-2)	3 (1-9)	0.999	-	3 (1-7)	-	-	5 (2-8)	2 (2-2)	2.5 (1-9)	0.700
Days of G-CSF used	6 (5-6)	6 (4-8)	6 (5-7)	11 (4-17)	**0.017***	6 (6-7)	10 (6-15)	**0.013***	7	10 (6-14)	6 (5-7)	9 (4-17)	**0.001***
Cell count, million/kg	2.4 (0.2-6.8)	6.4 (6-6.8)	2.6 (0.5-6.2)	6.8 (2-7.9)	**0.001***	3.9 (2-7)	7.5 (0.8-12.4)	0.181	4.6	5.5 (3-8)	3 (0.2-7)	6.8 (0.8-12.4)	**< 0.001***
Autologous transplant, n (%)													
No	4(57.1)	-	5 (33.3)	2 (15.4)	0.512	4 (50.0)	1 (16.7)	0.469	-	1 (50.0)	13 (41.9)	4 (17.4)	0.077
Yes	3 (42.9)	2 (100.0)	10 (66.7)	11 (84.6)		4 (50.0)	5 (83.3)		1 (100.0)	1 (50.0)	18 (58.1)	19 (82.6)	

Hgb = hemoglobin, PLT = platelet, WBC = leukocyte, ANC = neutrophil, CT = chemotherapy, HL = Hodgkin lymphoma, NHL = Non-Hodgkin lymphoma, MM = multiple myeloma

CSF and plerixafor and chemotherapy plus G-CSF and plerixafor groups showed no significant difference for other short-term findings.

DISCUSSION

A number of literature reviews describing the role of plerixafor in HSC mobilization have been published [20].This study retrospectively compared the results of mobilization with G-CSF and plerixafor and CT plus G-CSF and plerixafor in different patient groups with a history of mobilization failure. The study aimed to evaluate the increase in the number of CD 34+ cells in peripheral blood after plerixafor administration for the two mobilization regimens, the percentage of patients made eligible for ASCT, the engraftment kinetics of ASCT and their OS results.

The study by Hübel *et al*. [21] including 60 patients reported that mobilization with plerixafor provided the minimum of 2 × 106 CD34+ cells/kg required for successful mobilization [21]. In the present study, successful mobilization with plerixafor was achieved in patients. In a total study population of 56 patients, Duarte *et al*. [22] reported that ≥ 2 × 106 CD 34 cells/kg were collected using G-CSF in 42 (75%) patients collecte. In 115 patients with reported mobilization failure, Calandra *et al*. [23] reported that mobilization with G-CSF and plerixafor achieved a successful mobilization rate of 66% in their total study population - 60.3% in NHL, 71.4% in MM and 76.5% in HL. Tricot *et al*. [24] reported a rate of successful

Table 6. Engraftment data of patients who underwent ASCT

Variables	HL n = 5	NHL n = 21	MM n = 9	Other n = 2	Total n = 54	*p value*
PLT engraftment, > 20k (days)						
Early mortality, n (%)	-	2 (9.5)	-	-	2(5.4)	0.589
Poor, n (%)	1 (20.0)	3 (14.3)	-	-	4(10.8)	
Measurable, n (%)	4(80.0)	16(76.2)	9 (100.0)	2 (100.0)	31 (83.8)	
PLT engraftment	11 (11-15)	20 (12-123)	14 (10-25)	21.5 (11-32)	15 (10-123)	**0.014***
PLT engraftment, > 50k (days)						
Early mortality, n (%)	-	2 (9.5)	-	-	2 (5.4)	0.390
Poor, n (%)	1 (20.0)	5 (23.8)	-	-	6 (16.2)	
Measurable, n (%)	4 (80.0)	14 (66.7)	9 (100.0)	2 (100.0)	29 (78.4)	
PLT engraftment	16 (13-22)	25 (16-180)	16 (12-37)	27.5 (18-37)	21 (12-180)	**0.049***
Neutrophil engraftment, > 500/ x10^3/µl (days)						
Early mortality, n (%)	-	2 (9.5)	-	-	2 (5.4)	0.999
Poor, n (%)	-	1 (4.8)	-	-	1 (2.7)	
Measurable, n (%)	5 (100.0)	18 (85.7)	9 (100.0)	2 (100.0)	34 (91.9)	
Neutrophil engraftment	**10(10-12)**	12(10-34)	13(11-19)	11(11-11)	12(10-34)	0.050*
Neutrophil engraftment, > 1000 x103/µl (days)						
Early mortality, n (%)	-	2 (9.5)	-	-	2 (5.4)	0.999
Poor, n (%)	-	1 (4.8)	-	-	1 (2.7)	
Measurable, n (%)	5 (100.0)	18 (85.7)	9 (100.0)	2 (100.0)	34 (91.9)	
Neutrophil engraftment	12 (11-14)	13 (11-60)	13 (12-52)	11.5 (11-12)	13 (11-60)	0.241

PLT = platelet, HL = Hodgkin lymphoma, NHL = Non-Hodgkin lymphoma, MM = multiple myeloma

mobilization of 85% in 20 MM patients. Micallef *et al*. [25] reported a rate of successful mobilization of 63.5% in 298 NHL patients, and the reported rate of successful mobilization in 20 patients otherwise eligible for ASCT who failed previous mobilization attempts in the study by Fowler *et al*. was 85% 26. The present study in line with previous data reported a rate of successful mobilization in NHL, MM and HL.

The aforementioned results were in line with the study of Hüber *et al*. [21], who reported time to neutrophil and platelet engraftment as 12 days and 16 days, respectively, and with the study of Calandra *et al*. [23], who reported time to neutrophil and platelet engraftment as 10 days and 16 days, respectively. In the study by Dipersio *et al*. [27], time to neutrophil and platelet engraftment in MM patients mobilized with plerixafor was 11 days and 18 days, respectively while Flomenberg *et al*. [28] reported time to median neutrophil and platelet engraftment in MM patients mobilized with plerixafor containing regimen as 10.5 and 21 days, respectively. In a single-center series with similar findings in terms of safety and efficacy, notably of 33 childeren mobilized with G-CSF plus plerixafor in Moscow that included evidence of satisfactory engraftment [29]. In the present study, time to neutrophil and platelet engraftment in MM patients was 13 days and 14 days, respectively. The different diagnostic groups showed no significant difference with regards to time to engraftment.

One randomized blind placebo-controlled phase III trial including 298 NHL patients and another study including 302 MM patients demonstrated that addition of plerixafor to G-CSF results in a significantly higher yield of CD34+ cells and fewer days of apheresis for sufficient mobilization [18, 19]. In G-CSF and plerixafor group, the percentage of patients having required ≥ 2 days of apheresis was higher, while the median days of G-CSF administered and median count of CD34+ cells mobilized were lower compared to the CT plus G-CSF and plerixafor group.

Mobilization regimens including CT are associated with risk of secondary malignancy, infertility, cardiac toxicity, cytopenia and infection, which in turn lead to increase in treatment costs30-33. In our study, the rate of febrile neutropenia, the percentage of patients requiring transfusions, median days of G-CSF administered and median CD34+ cell count were significantly higher in the CT plus G-CSF and plerixafor group compared to G-CSF and plerixafor group.

Previous studies have demonstrated correlation between successful mobilization and certain factors including peripheral leukocyte count, platelet count [34-36]. Among our patients who underwent ASCT, mean Hgb level, median platelet count and median leukocyte count on the day of plerixafor administration were higher in the G-CSF and plerixafor group compared to CT plus G-CSF and plerixafor group.

Previous studies demonstrated that intensive radiotherapy and use of lenalidomide have adverse effects on stem cell mobilization [37-40]. Although recent studies recommend the use of the immunomodulator agent lenalidomide in induction treatment for MM, use of lenalidomide for MM induction treatment was shown to compromise stem cell mobilization [40, 41]. With the "just-in-time" application of plerixafor [42], in view of a low CD34+ cell count (< 10/mμ) on the anticipated first apheresis day, an adequate numbers of CD34+ cells were mobilized and collected, able to support one or two further cycles of HDC. In our study group, the mobilization outcomes showed no statistical difference for the 10 patients with previous history of radiotherapy. Moreover, in our study group, 55.6% of the MM patients who underwent transplantation had history of lenalidomide use.

Limitations

The limitation of our study is retrospective and the number of cases examined is low, disease invetstigated were too many in this manuscript. A prospective study may be useful in this area.

CONCLUSION

In conclusion, our study demonstrated that administration of plerixafor is generally safe and well-tolerated. Regardless of the underlying disease, it offers an effective alternative for patients with previous failed mobilization attempts using conventional regimens, and allows stem cell collection with fewer apheresis sessions.

Authors' Contribution

Study Conception: SS; Study Design: SS, İYH; Supervision: FDS; Funding: N/A; Materials: HSB, SKB; Data Collection and/or Processing: YGM, TOT;

Statistical Analysis and/or Data Interpretation: ÖGS, FH; Literature Review: AİG, ÖGS; Manuscript Preparation: SS and Critical Review: MN, FDS.

Conflict of interest

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

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