

ORIGINAL ARTICLE

G-CSF plus preemptive plerixafor vs hyperfractionated CY plus G-CSF for autologous stem cell mobilization in multiple myeloma: effectiveness, safety and cost analysis

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The optimal stem cell mobilization regimen for patients with multiple myeloma (MM) remains undefined. We retrospectively compared our experience in hematopoietic cell mobilization in 83 MM patients using fractionated high-dose CY and G-CSF with G-CSF plus preemptive plerixafor. All patients in the CY group ($n = 56$) received fractionated high-dose CY (5 g/m^2 divided into five doses of 1 g/m^2 every 3 h) with G-CSF. All patients in the plerixafor group ($n = 27$) received G-CSF and plerixafor preemptively based on an established algorithm. Compared with plerixafor, CY use was associated with higher total CD34+ cell yield (7.5×10^6 vs 15.5×10^6 cells/kg, $P = 0.005$). All patients in both groups yielded $\geq 4 \times 10^6$ CD34+ cells/kg. Conversely, CY use was associated with high frequency of febrile neutropenia, blood and platelet transfusions need and hospitalizations. The average total cost of mobilization in Lebanon was slightly higher in the plerixafor group ($\$7886$ vs $\$7536$; $P = 0.16$). Our data indicate robust stem cell mobilization in MM patients with either fractionated high-dose CY and G-CSF or G-CSF alone with preemptive plerixafor. The chemo-mobilization approach was associated with twofold stem cell yield, slightly lower cost but significantly increased toxicity.

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INTRODUCTION

Multiple myeloma (MM) accounts for 10% of all hematological malignancies in the United States.¹ MM remains incurable and the aim of treatment in non-elderly patients, in general < 65 years, is to prolong survival using chemotherapy, corticosteroids and/or novel agents such as bortezomib or lenalidomide followed by high-dose chemotherapy and auto-SCT, which has been shown to be superior to conventional chemotherapy alone.^{2–4} The optimal regimen to mobilize stem cells in patients with MM is still controversial and has not been clearly defined. The mobilization strategies implemented by most transplant centers consist of G-CSF alone (steady-state strategy) or CY followed by G-CSF (chemo-mobilizing strategy).^{5–14} However, the impact of CY dose on stem cell yield, subsequent engraftment and toxicity remains a matter of controversy. Moreover, the introduction of the new mobilizing agent, plerixafor, an inhibitor of stromal cell-derived factor 1 α /C-X-C chemokine receptor type 4,^{15,16} makes the choice of mobilization strategy even more controversial. Upon its introduction, plerixafor has been used successfully along with G-CSF specifically in patients either failing or likely to fail standard mobilization with growth factor or growth factor combined with chemotherapy.^{17,18} The high cost of plerixafor led many investigators to introduce it in a preemptive strategy, which could even be more cost-effective than CY followed by G-CSF.^{19,20} Very few studies compared efficacy, toxicity and cost-effectiveness of stem cell mobilization with CY and G-CSF vs G-CSF with preemptive plerixafor. In this study, we retrospectively reviewed our single-center experience at the American University of Beirut Medical Center in transplant-eligible MM patients using fractionated high-

dose CY and G-CSF as our past preferred chemo-mobilization strategy compared with our new mobilization strategy using G-CSF plus preemptive plerixafor. The change in practice was implemented when plerixafor became available in the country, in order to circumvent CY-associated toxicity.

MATERIALS AND METHODS

Patient population

We conducted a single institution retrospective analysis on 83 consecutive hematopoietic stem cell mobilization attempts performed in patients with MM. Among them, 56 patients had received fractionated high-dose CY and G-CSF as chemo-mobilization strategy (CY group) and 27 patients underwent mobilization with G-CSF and preemptive plerixafor (plerixafor group). This study was approved by the institutional review board of the American University of Beirut Medical Center and was conducted in accordance with the principles of the Declaration of Helsinki.

Patient characteristics

Overall, 27 patients (18 mobilized with G-CSF and 9 requiring G-CSF and plerixafor) were included in the plerixafor group and 56 were included in the CY group. Patients in the plerixafor group underwent mobilization in more recent years (in 2013 and 2014), whereas patients in the CY group underwent mobilization before 2013. More patients in the plerixafor group had lenalidomide containing inductions (48% vs 2%) and a lower proportion of patients transplanted as first-line treatment.

Stem cell mobilization and collection

CY mobilization. In all patients in the CY group, hematopoietic stem cell mobilization was performed after completion of induction chemotherapy.

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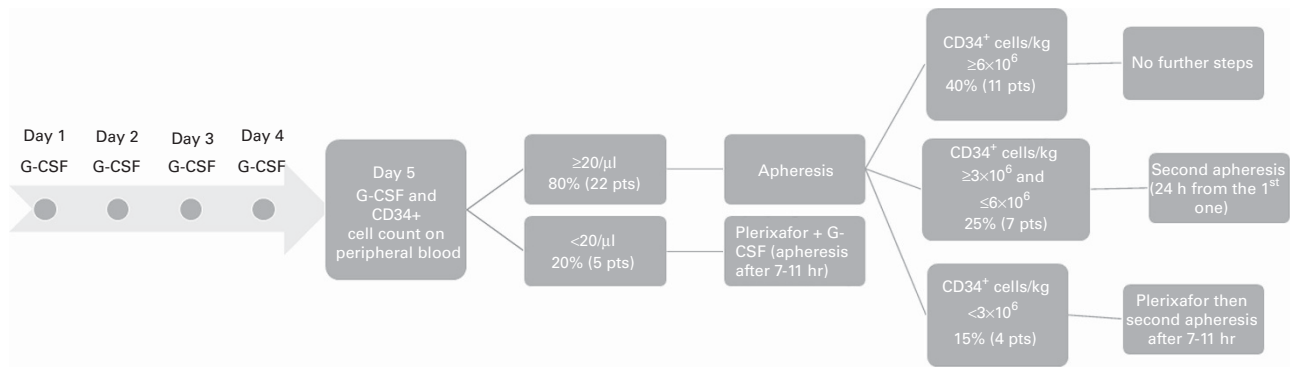


Figure 1. Plerixafor stem cell mobilization algorithm.

All patients received fractionated high-dose CY (5 g/m^2 divided in to five doses of 1 g/m^2 every 3 h) with mesna and i.v. fluid hydration. G-CSF was started on Day +6 of chemotherapy at a fixed dose of $300 \mu\text{g s.c.}$ every 12 h and was continued until completion of apheresis. Daily complete blood cell count was performed from Day +7, and once the WBC count reached $10\,000/\mu\text{L}$ or more, peripheral blood CD34 count was performed. When circulating CD34+ cell count was $\geq 20 \text{ cells}/\mu\text{L}$, apheresis was undertaken. All collections were performed with the COBE Spectra cell separator (Gambro BCT, Lakewood, CO, USA). A volume of 20–25 L of blood was processed during 4–5 h of apheresis. The target of collection was at least $4 \times 10^6/\text{kg}$ CD34+ cells to support two autografts. After performing a sterility testing (bacterial and fungal), the final products were frozen in 10% DMSO (final concentration) using a controlled rate freezing system (Thermo CryoMed, Thermo Electron Corporation, Model:7450, Marietta, OH, USA). The frozen products were stored at -196°C dipped in liquid nitrogen. Apheresis would be repeated on subsequent days until the target yield of CD34+ cells was reached. After conditioning therapy, the ordered CD34+ cells were quickly thawed at $37\text{--}40^\circ\text{C}$ in a water bath. Moreover, a viability test was performed on each of the thawed collects using Trypan-blue stain (The percentage of viable cells were calculated.). Stem cells would then be transfused to the patient over 10–15 min.

Plerixafor mobilization algorithm. We followed a decision-making algorithm that uses CD34+ cell count in peripheral blood on the fifth day of mobilization with G-CSF and the target number of CD34+ cells to be collected to decide whether to use plerixafor or not. These algorithms are cost-effective and have been implemented by other investigators.^{21–23} All patients in the plerixafor group received G-CSF at a fixed dose of $300 \mu\text{g s.c.}$ every 12 h daily for 4 days. On Day 5, if peripheral blood CD34+ cell count was $\geq 20 \text{ cells}/\mu\text{L}$, apheresis was started immediately. Plerixafor ($240 \mu\text{g}/\text{kg}$) was given 7–11 h before the first apheresis if CD34+ cell count on peripheral blood on Day 5 was $< 20 \text{ cells}/\mu\text{L}$ and before the second apheresis if CD34+ cell count on the first collection was $< 3 \times 10^6/\text{kg}$ (Figure 1). Apheresis equipment and procedures were identical to those described above for the CY group.

Statistical analysis

All statistical analyses were performed using the SPSS software, version 17 (SPSS Inc., Chicago, IL, USA). Continuous variables were presented by their median and range, whereas categorical variables by their relative frequencies and counts. Pearson's Chi-square/Fisher's exact test and Student's *t*-test were used to compare categorical and continuous variables, respectively. Results were considered significant at $P < 0.05$ based on two-sided tests.

RESULTS

Mobilization efficiency

The baseline characteristics of 83 consecutive patients included in this analysis are summarized in Table 1. All 56 (100%) patients in the CY group and 22 patients (80%) in the plerixafor group achieved a circulating CD34+ cell count $\geq 20 \text{ cells}/\mu\text{L}$, which is the cutoff level at our institution to proceed directly with apheresis. Four of the patients in the plerixafor group had inadequate CD34+

cell yields after the first apheresis ($< 3 \times 10^6$) and received plerixafor before the second apheresis. The remaining five patients (20%) in the plerixafor group achieved a circulating CD34+ cell count $< 20 \text{ cells}/\mu\text{L}$ and hence required plerixafor prior to the first apheresis (Figure 1).

Compared with preemptive plerixafor use, CY was associated with higher median peak peripheral blood CD34+ cell counts (35 vs $111.5 \text{ cells}/\mu\text{L}$, $P < 0.0001$), and total CD34+ cell yield (7.5×10^6 vs $15.5 \times 10^6 \text{ cells}/\text{kg}$, $P = 0.005$). Moreover, 54 (96%) and 40 (70%) patients in the CY group vs 24 (88.8%) and 6 (22%) patients in the plerixafor group yielded $\geq 6 \times 10^6$ and $\geq 10 \times 10^6$ CD34+ cells/kg, respectively ($P = 0.176$; $P < 0.0001$). All patients in both groups yielded $\geq 4 \times 10^6$ CD34+ cells/kg, which certainly was sufficient to perform two autografts (tandem or possible future transplant in case of disease progression/relapse). Only 4 (7%) patients required two apheresis sessions in the CY group compared with 11 (40%) in the plerixafor group ($P = 0.0002$). No one required more than two apheresis sessions (Table 2). Finally, the median number of days of G-CSF required for stem cell mobilization in the CY group was 10 (range: 7–15) and the median time from CY to stem cell collection was 12.5 days (range: 7–19).

Toxicity and supportive care

Plerixafor was generally safe with no associated toxicities. Conversely, CY use was associated with a high frequency of febrile neutropenia (60%), blood transfusions (27%; median number of transfusions = 2), platelet transfusions (27%; median number of transfusions = 1) and hospitalizations (64%; median days of hospitalization = 4 days). None of the patients required intensive level of care and all recovered.

Transplantation and engraftment

Autografting was successfully performed in all patients using high-dose melphalan with a median time from mobilization to the first transplant of 30 days (range: 16–156) in the CY group compared with 13 days (range: 8–40) in the plerixafor group ($P = 0.0002$); and median infused CD34+ cell count was $7 \times 10^6/\text{kg}$ (range: 3.1–15.3) vs 5.27 (2.6–7.45), respectively ($P = 0.002$). Median time to neutrophil engraftment was 11 days (8–19) in the CY group compared with 12 days (10–15) in the plerixafor group ($P = 0.027$). Similarly, median time to platelet engraftment was 12 days (6–22) in the CY group compared with 12 days (8–19) in the plerixafor group ($P = 0.12$).

Comparative cost analysis

We performed a comparative analysis of average costs associated with each of the mobilization strategies (chemo-mobilizing approach vs G-CSF and preemptive plerixafor approach). Our institution's billing office provided us with the cost data for

Table 1. Patient characteristics, treatment and response

Variables	CY arm (N = 56)	Plerixafor arm (N = 27)	P-value
Male/female	33/23	18/9	0.236
Age at transplant, median (range), years	54.5 (37–75)	54 (35–66)	0.514
<i>Disease isotype</i>			
IgG	28 (50%)	17 (63%)	0.267
Light chain only	15 (27%)	4 (15%)	0.275
IgA	12 (21%)	6 (22%)	0.934
Non-secretory	1 (2%)	0 (0%)	1
<i>ISS staging</i>			
I	31 (55%)	15 (55%)	0.986
II	15 (27%)	2 (8%)	0.046
III	10 (18%)	10 (37%)	0.056
Serum creatinine > 2.0 mg/dL	8 (14%)	4 (15%)	1
<i>Cytogenetic abnormalities</i>			
Normal karyotype	16 (29%)	13 (47%)	0.08
t(4;14)	5 (9%) ^a	1 (3%) ^a	0.658
Del 17p	1 (2%)	1 (3%)	0.547
Del 13q	2 (3%) ^a	1 (3%) ^a	1
Unavailable/missing	32 (57%)	12 (44%)	0.278
<i>Disease phase at transplant</i>			
First line	48 (85%)	18 (67%)	0.044
More advanced	8 (15%)	9 (33%)	0.044
<i>Induction therapy</i>			
Vincristin/Adriamycin/ Dexamethasone	25 (44%)	0 (0%)	< 0.0001
Bortezomib/ Dexamethasone	9 (16%)	8 (30%)	0.152
Thalidomide/ Dexamethasone	10 (18%)	0 (0%)	0.026
Bortezomib/ Thalidomide/ Dexamethasone	10 (18%)	4 (15%)	1
Bortezomib/ lenalidomide/ Dexamethasone	1 (2%)	12 (45%)	< 0.0001
CY/Thalidomide/ Dexamethasone	0 (0%)	2 (7%)	0.103
CY/lenalidomide/ Dexamethasone	0 (0%)	1 (3%)	0.325
Vincristin/CY/ Adriamycin/ Prednisolone	1 (2%)	0 (0%)	1
<i>Disease status prior to autologous HSCT^b</i>			
CR	7 (13%)	1 (4%)	0.264
Very good PR	7 (13%)	8 (30%)	0.057
PR	42 (74%)	18 (66%)	0.257

Abbreviations: HSCT = hematopoietic SCT; ISS = International Staging System. ^aOne patient had both t(4;14) and Del 13q. ^bInternational Myeloma Working Group Uniform Response Criteria.

hospitalizations related to mobilization (chemotherapy, central catheter insertion, hospitalization for neutropenic fever, supportive care, apheresis and physicians' fees). These costs were adjusted based on the estimates of the Lebanese National Social Security Fund (NSSF). We added the cost of G-CSF and plerixafor that the patients have received outside of their hospitalizations. We calculated the average costs of mobilization for the CY group

for the year 2012 only ($n = 10$) (the last update of prices in our institution was in 2011) and for the plerixafor group on all patients. Overall, the average cost of mobilization was \$7536 for the CY group (Figure 2) and \$7886 for the plerixafor group (Figure 3).

DISCUSSION

In this report, we have compared the efficacy and outcome of peripheral blood stem cell mobilization following a CY-based strategy against a preemptive plerixafor strategy in a single institution cohort of MM patients. Our data suggest that the yield of stem cell mobilization was twofold higher when using fractionated high-dose CY compared with preemptive plerixafor strategy (15.5×10^6 vs 7.5×10^6 cells/kg, $P = 0.005$). However, the CY protocol was associated with a higher incidence of febrile neutropenia, transfusion requirements and hospitalizations. In addition, plerixafor was associated with slightly higher cost, albeit not statistically significant, compared with the CY-based strategy (\$7886 vs \$7536; $P = 0.16$).

G-CSF alone is an inferior mobilization regimen when compared with CY and growth factors especially in heavily pretreated MM patients or with prior exposure to lenalidomide or radiotherapy.^{24,25} Interestingly, the imbalance in lenalidomide use between both arms is in favor of the plerixafor arm as patients in this arm were more likely to receive lenalidomide during induction.

High-dose CY with G-CSF has been shown to be an effective regimen for collecting peripheral blood progenitor cells in MM patients, but the optimal dose to be used remains controversial. The dose of CY reported for mobilization has ranged from 1.5 to 7 g/m². Retrospective studies comparing different CY doses have shown a higher CD34+ cell yield associated with higher dose of CY but with more considerable toxicity, which limits the use of very high dose CY (7 g/m²) and favor the use of intermediate-to-high dose.^{6,8,9} Indeed, fractionation of CY in our study allowed administration of a relatively high dose of CY (5 g/m²) with decreased immediate toxicity, mainly nausea and vomiting, but was still associated with significant hematological toxicity.

The incorporation of plerixafor into clinical practice for hematopoietic stem cell mobilization continues to be further refined. The concomitant use of plerixafor with G-CSF resulted in improvement in the yield of CD34+ cells compared with G-CSF alone in patients with MM and non-Hodgkin's lymphoma.^{26–29} The safety and efficacy of plerixafor has been proven in several studies,^{17,30} which included heavily pretreated patients.¹⁸ Moreover, plerixafor has been shown to be feasible to combine with chemotherapy and G-CSF in predicted poor mobilizers with MM or lymphoma.³¹ However, the major limitation to the use of plerixafor is related to high cost. To solve this problem, many investigators have developed algorithms for same day decision on the use of plerixafor based on peripheral blood CD34+ cell count on the fourth or fifth day of mobilization.^{21–23} These algorithms may offset the high toxicity associated with CY use and the excessive cost associated with unnecessary use of plerixafor in patients for whom G-CSF mobilization alone would suffice. Very few studies compared efficacy, toxicity and cost-effectiveness of stem cell mobilization with CY and G-CSF vs G-CSF with preemptive plerixafor. Costa *et al.*²⁰ showed in a retrospective single institution study that G-CSF with preemptive plerixafor is superior to intermediate-dose CY-based mobilization for autologous hematopoietic stem cell mobilization in terms of safety, efficiency and no difference in mobilization cost. On the other hand, Awan *et al.*³² compared intermediate-dose CY-based mobilization with G-CSF with preemptive plerixafor and showed a comparable efficacy and lower cost with higher but manageable toxicity in favor of CY strategy.

Table 2. Mobilization/apheresis outcomes

Variables	CY arm (N = 56)	Plerixafor arm (N = 27)	P-value
Peak peripheral blood CD34+ cell count, cells/ μ L; median (range)	111.5 (21–575)	35 (5–141)	< 0.0001
Total CD34+ cells $\times 10^6$ /kg collected, median (range)	15.5 (4.2–211)	7.5 (4–14.8)	0.005
Total number of apheresis sessions, median (range)	1 (1–2)	1 (1–2)	0.0002
<i>N (%) patients collecting</i>			
$\geq 6 \times 10^6$ CD34+ cells/kg	54 (96%)	24 (88%)	0.176
$\geq 10 \times 10^6$ CD34+ cells/kg	40 (71%)	6 (22%)	< 0.0001

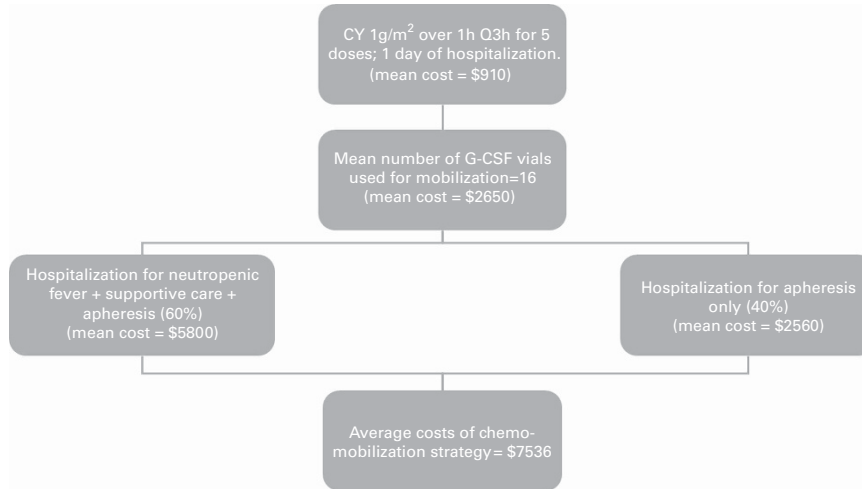


Figure 2. Average cost of chemo-mobilization strategy.

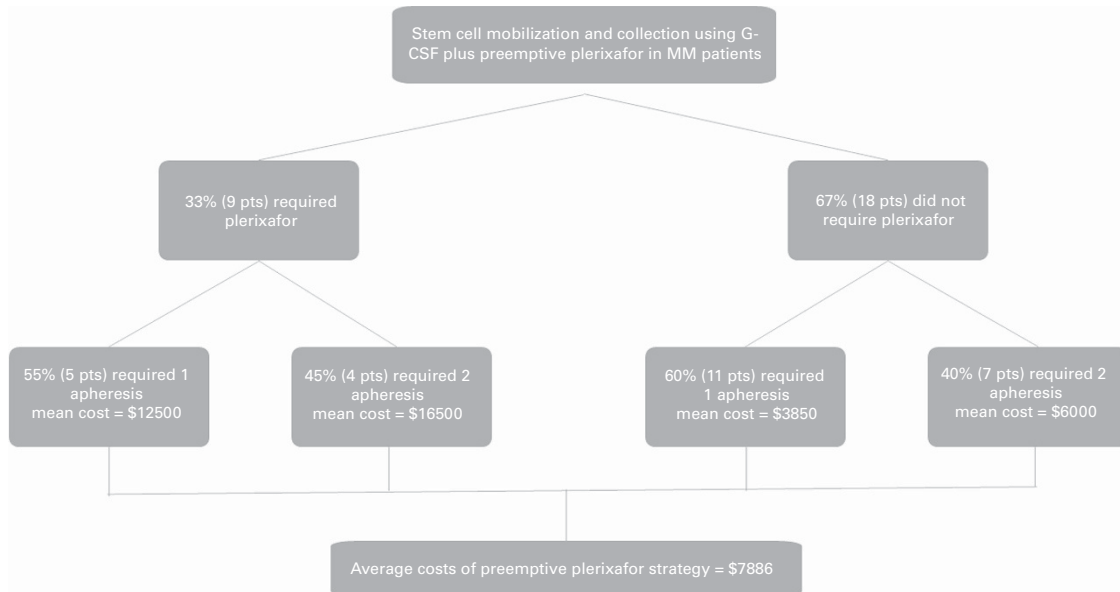


Figure 3. Average cost of preemptive plerixafor strategy.

We acknowledge several limitations in our analysis. For instance, it represents a retrospective study with inherent limitations. Also, it includes a relatively small sample size from a single center. In addition, more patients in the plerixafor group had lenalidomide-containing inductions (48% vs 2%) and higher proportion of patients transplanted with more advanced disease

phase (33% vs 15%), which might have adversely affected cell yield in the plerixafor arm.

In this report, we demonstrated that both preemptive plerixafor and fractionated high-dose CY plus G-CSF are highly effective stem cell mobilization strategies in MM patients. The chemo-mobilization approach was associated with twofold

stem cell yield, slightly lower cost but significantly increased toxicity.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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