Efficacy, safety, and cost of mobilization strategies in multiple myeloma: a prospective, observational study

High-dose therapy followed by autologous hematopoietic cell transplant (AHCT) has been the standard-of-care for eligible patients with newly diagnosed multiple myeloma.[1,2] Mobilization of peripheral blood hematopoietic stem and progenitor cells (HSPC) can be accomplished using either granulocyte colony-stimulating factor (G-CSF) alone or in combination with chemotherapy (cyclophosphamide 3 g/m^2) or plerixafor.[3,4] None of these strategies has been prospectively compared. Given the higher drug costs of plerixafor, its use has been limited in several centers as a rescue in patients at high risk of mobilization failure with G-CSF alone (the so-called "just-in-time" [JIT] approach). In this prospective, multicenter, observational study, we sought to evaluate the efficacy of various mobilization regimens and their impact on post-AHCT outcomes and conduct a health economics analysis in Medicare beneficiaries.

Eligibility criteria included patients 18-70 years of age undergoing AHCT within 12 months of induction treatment for multiple myeloma and reported consecutively from participating Center for International Blood and Marrow Transplant Research (CIBMTR) centers (N=20) (NCT 03200626). For the health economic analysis, we used an independent dataset from the Centers for Medicare and Medicaid Services (CMS) of Medicare patients merged with the CIBMTR database who underwent first AHCT in 2016 in the USA.

The primary objective of the prospective study was to compare the total CD34$^+$ cell yield of HSPC mobilization in patients with multiple myeloma undergoing mobilization with: (i) a G-CSF-based strategy (alone or using JIT plerixafor; G±JIT cohort), (ii) a planned G-CSF and plerixafor combination (G+P), and (iii) G-CSF plus chemomobilization (G+C), (*Online Supplementary Table S1*). The objective of the health economics analysis was to determine service utilization and costs associated with mobilization regimens and was a retrospective analysis of a separate cohort of Medicare beneficiaries who underwent transplants in 2016 comparing: (i) G-CSF alone (G), (ii) G-CSF plus plerixafor, planned or JIT (G+P or JIT), and (iii) G-CSF ± plerixafor plus chemomobilization (G+C).

Patient- and transplant-related characteristics were described and compared between the three mobilization strategies. A Cox proportional hazards model and a Fine and Gray subdistribution hazards model including patient-, disease- and treatment-related variables were used to assess hematopoietic recovery, non-relapse mortality, relapse/progression, progression-free survival and overall survival.

For the cost analysis, observable total Medicare allowable costs associated with service resources utilized during mobilization were estimated in 2016 US dollars. *Post-hoc* analyses were conducted to compare outpatient costs and total costs between pair groups by mobilization strategy for each period. The method of cost-to-charge ratio analysis was applied to estimate total inpatient and outpatient costs from the provider's perspective.

A total of 750 patients were enrolled of whom 744 met all inclusion criteria (*Online Supplementary Table S1*). The three groups were well balanced overall. Twenty patients in the G+C group received plerixafor as rescue. Twelve patients underwent a second mobilization attempt.

Table 1 summarizes the efficacy parameters of the three mobilization strategies. The median CD34$^+$ cell yield in the first apheresis session was significantly lower in the G±JIT cohort (4.7x10^6/kg) than in the G+P cohort (6.4x10^6/kg) or G+C cohort (6x10^6/kg) (P<0.01). The total CD34$^+$ cell yield was also significantly lower in the G±JIT cohort (8x10^6/kg *vs*. 8.8 x10^6/kg in the G+P cohort and 9.3x10^6/kg in the G+C cohort; P<0.01. A higher proportion of patients in the G+P cohort required two or fewer total apheresis sessions (86%) compared to the proportions in the G±JIT (70%) and G+C (74%) cohorts (P<0.01). The total number of G-CSF doses administered was higher in the G+C group (8-14 doses used in 68% of the G+C group, 18% of the G±JIT group and 9% of the G+P group; P<0.01). Overall, about 16% of patients failed to mobilize adequate HSPC for two transplants (based on the center's definition), with no difference between the groups.

About 23% of patients in the G+C group developed complications attributed to chemotherapy, including 4% who required hospitalization and 11% who had nausea/vomiting (Table 2). Among the G+C group, 12% received packed red cell transfusions, compared to 2% in the G±JIT group and 2% in the G+P group (P<0.01). Similarly, 10% of subjects received platelet transfusions in the G+C group, compared to 0.5% in the G±JIT group and 3% in the G+P group (P<0.01). On multivariate analysis, the rates of neutrophil and platelet engraftment were significantly higher in the G+P and G+C groups than in the G±JIT group but no difference was observed in non-relapse mortality, relapse, progression-free survival or overall survival (*Online Supplementary Table S2*). Myeloma remained the primary cause of death in all groups.

For the health economics analysis, a total 222 patients in the CIBMTR-Medicare merged dataset met the inclusion criteria. In the pre-apheresis period, patients in the G+C

cohort had more outpatient visits and a higher number of outpatient prescriptions filled (*Online Supplementary Table S3*). The median costs for the entire mobilization strategy were $23,033 (interquartile range [IQR] $15,512) for the G+P or JIT group, $19,522 (IQR $10,132) for the G+C group, and $11,191 (IQR $9,695) for the G alone group (*P*<0.0001) (Figure 1A, *Online Supplementary Table S3*).

The median total costs were further examined by payment type and mobilization strategy (Figure 1B). Patients in the G+P or JIT group were responsible for 17% of the total payments, compared to 20% for the other two mobilization groups (*P*<0.001). The estimated median cost for drugs charged to patients (cost-to-charge ratio) was approximately $18,000 for the G+P or JIT and G+C groups, and approximately $7,000 for the G alone group.

In this largest prospective, observational study comparing three different mobilization regimens, we showed that the G+C and G+P approaches provided higher CD34$^+$ cells/kg yield on day 1 as well as total CD34$^+$ cell/kg yield, but there was no difference in mobilization failures or post-

Table 1. Efficacy of mobilization strategies.

	G±JIT (N=402)	G+P (N=269)	G+C (N=73)	*P* value (a,b,c = pairwise *P* values)
Peak CD34$^+$ cell count, cells/μL, median (IQR)	47.4 (27.9-66)	53.7 (14-94.5)	68 (23-147)	**0.22** 0.31[a] 0.13[b] 0.22[c]
Total CD34$^+$ cells on 1st apheresis, x10^6 cells/kg, median (IQR)	4.7 (2.4-7.8)	6.4 (3.7-10.4)	6 (2.7-13.3)	**<0.01** <0.01[a] <0.01[b] 0.98[c]
Total CD34$^+$ cell yield, x10^6 cells/kg, median (IQR)	8 (6.5-10.1)	8.8 (6.6-11.4)	9.3 (7.1-14.4)	**<0.01** <0.01[a] <0.01[b] 0.11[c]
Total number of days of apheresis collection, N (%) 1 day 2 days >2 days	 153 (38) 130 (32) 119 (30)	 149 (55) 84 (31) 36 (13)	 36 (49) 18 (25) 19 (26)	**<0.01** <0.01[a] <0.18[b] 0.03[c]
Total number of G-CSF doses administered, N (%) 1-7 8-14 >14 Not applicable Not reported	 321 (80) 72 (18) 7 (2) 0 (0) 2 (0)	 197 (73) 24 (9) 14 (5) 30 (11) 4 (1)	 9 (12) 50 (68) 13 (18) 0 (0) 1 (1)	**<0.01** <0.01[a] <0.01[b] <0.01[c]
Good mobilizer, N (%) No Yes Not reported	 104 (26) 291 (72) 7 (2)	 41 (15) 217 (81) 11 (4)	 17 (23) 55 (75) 1 (1)	**<0.01** <0.01[a] 0.87[b] 0.16[c]
Cells for 2 rounds of AHCT, N (%) No Yes Not reported	 66 (16) 329 (82) 7 (2)	 43 (16) 215 (80) 11 (4)	 12 (16) 60 (82) 1 (1)	**0.40** 0.18[a] 0.97[b] 0.53[c]
Mobilization failure, N (%) No Yes Not reported	 390 (97) 5 (1) 7 (2)	 255 (95) 3 (1) 11 (4)	 72 (99) 0 (0) 1 (1)	**0.29** 0.18[a] 0.61[b] 0.35[c]
Underwent apheresis on Saturday and Sunday, N (%) No Yes	 382 (95) 20 (5)	 266 (99) 3 (1)	 66 (90) 7 (10)	**<0.01** <0.01[a] 0.12[b] <0.01[c]
Stayed at a center closer to mobilization, N (%) No Yes Not reported	 163 (41) 165 (41) 74 (18)	 218 (81) 39 (14) 2 (4)	 65 (89) 7 (10) 1 (1)	**<0.01** <0.01[a] <0.01[b] 0.23[c]

G±JIT: granulocyte colony-stimulating factor (G-CSF) with or without "just in time" plerixafor; G+P: G-CSF plus plerixafor; G+C: G-CSF plus cyclophosphamide; IQR: interquartile range; AHCT: autologous hematopoietic cell transplantation. Pairwise *P* values: [a]G±JIT *vs.* G+P; [b]G±JIT *vs.* G+C; [c]G+P *vs.* G+C.

AHCT outcomes. G+C was associated with higher rates of hospitalization, gastrointestinal symptoms (nausea and vomiting) and transfusion requirements. From the health economic perspective, we showed that patients in the G+C group incurred the highest median total costs during the pre-apheresis period, while patients in the G+P or JIT group incurred the highest median total costs during the apheresis period.

G-CSF alone was found to be inferior to G+P and chemomobilization in several studies.[5,6] Studies comparing the JIT plerixafor approach to chemomobilization have produced divergent results.[7,8] The current observational study demonstrated superior efficacy with both G+C and routine G+P based approaches, compared to the G±JIT approach in terms of total number of cells collected, but there was no difference in mobilization failures or cells collected for two AHCT. Patients in the G+C and G±JIT groups required a higher number of apheresis sessions and a higher number of G-CSF doses to reach the collection target goal, consistent with previous studies.[6] It important to acknowledge that CD34+ collection targets vary across centers, but most collect enough cells for more than two

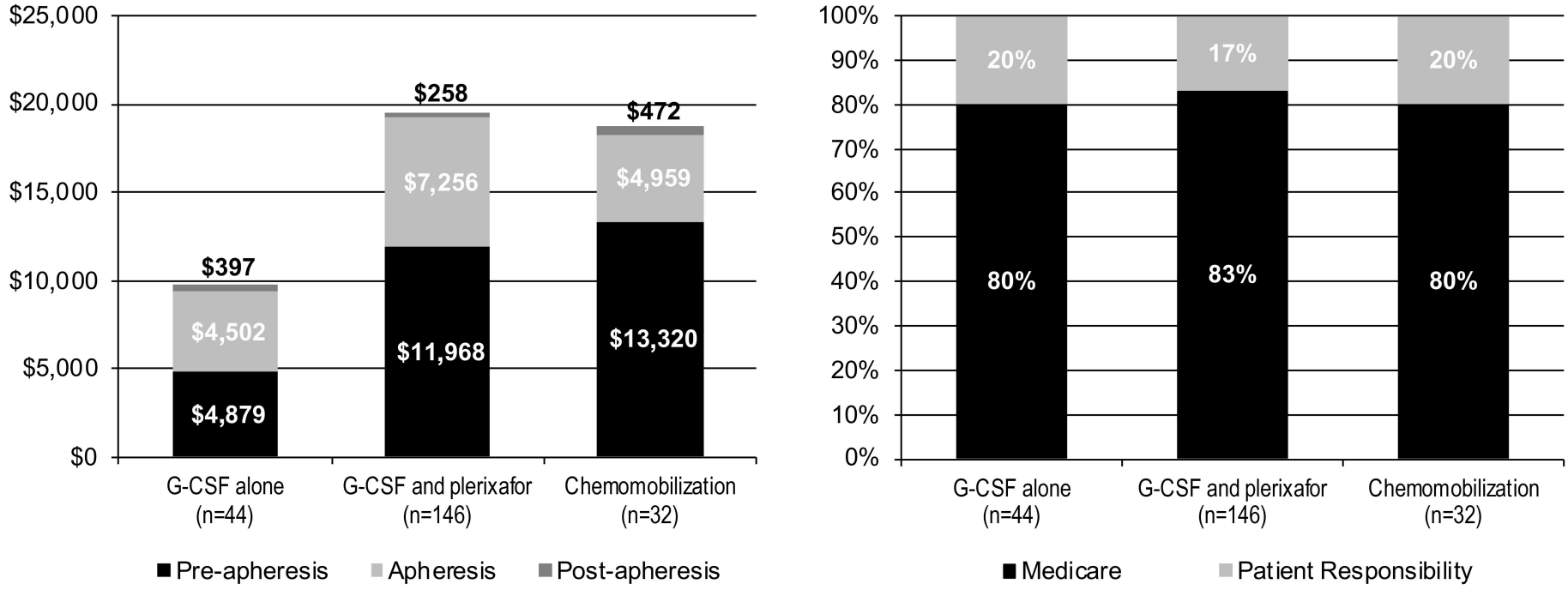

Figure 1. Costs by mobilization strategy. (A) Median total costs by time period and mobilization strategy in the health economics set. Note that the median total costs varied by mobilization strategy in the pre-apheresis period (P<0.0001). Total costs include inpatient, outpatient, home healthcare, and outpatient pharmacy costs. (B) Median percent of total costs by payment type and mobilization strategy. Note that both Medicare payment and "patient responsibility" varied by mobilization strategy (both P<0.0001). Patient responsibility included co-payment, co-insurance, and deductibles. The number of patients with a secondary payer was less than 11 (not reported). Total costs include inpatient, outpatient, home healthcare, and outpatient pharmacy costs. G-CSF: granulocyte colony-stimulating factor.

Table 2. Toxicity by mobilization strategies.

	G±JIT (N=402)	G+P (N=269)	G+C (N=73)	*P* value
Complications from chemotherapy, N (%)				Not applicable
None	0 (0)	0 (0)	56 (77)	
Hospitalization ± other	0 (0)	0 (0)	3 (4)	
Nausea ± other	(0)	0 (0)	8 (11)	
Other	0 (0)	0 (0)	5 (7)	
Not reported	(0)	0 (0)	1 (1)	
Not applicable	402 (100)	269 (100)	0 (0)	
Blood transfusion during apheresis, N (%)				<0.01
1 unit	7 (2)	4 (1)	7 (10)	
>1 unit	1 (0)	2 (1)	2 (3)	
Platelet transfusion during apheresis, N (%)				<0.01
1 unit	2 (0)	7 (3)	6 (8)	
>1 unit	0 (0)	0 (0)	1 (1)	
Not reported	0 (0)	1 (0)	0 (0)	

G±JIT: granulocyte colony-stimulating factor (G-CSF) with or without "just in time" plerixafor; G+P: G-CSF plus plerixafor; G+C: G-CSF plus cyclophosphamide.

AHCT. To account for variation across centers for collection targets, we defined a good mobilizer as a patient from whom it was possible to collect ≥5.0 x10^6 $CD34^+$ cells/kg in a maximum of two apheresis sessions. There were significantly higher numbers of good mobilizers in both the G+P (81%) and G+C (75%) cohorts than in the G±JIT (72%) cohort.

Chemomobilization has been shown to be associated with higher rates of hematologic and non-hematologic toxicities, consistent with our observations.[9-11] Interestingly the rates of hospitalization were much lower in our study (3%) than those reported in prior studies.[12]

A major limitation of our analysis is that while the claims data captured the use of plerixafor, they lacked the granularity to differentiate between how the drug was incorporated into mobilization (G+P or JIT). Thus, in the cost analysis we were not able to compare the costs of G±JIT against G+P; hence, the cost analysis groups were different from the grouping for efficacy analysis. A prior analysis comparing the cost of G+P *versus* G±JIT showed that the average estimated cost with routine plerixafor use was significantly higher than that with JIT use.[13] We showed that total costs were lowest for G-CSF alone and highest for G+P or JIT, and that drug cost, the key driver for all mobilization strategies, varied by period of mobilization. In the pre-apheresis period, G+C incurred the highest cost of the three mobilization strategies, likely associated with more outpatient visits and days of G-CSF use. During the apheresis period, G+P or JIT incurred the highest cost, driven likely by the cost of plerixafor. Prior cost analyses have shown varying results in single institution studies. For example, Afifi *et al*. showed that the high cost of plerixafor in the G±JIT group was offset by increased resource utilization in the G+C (cyclophosphamide 3 g/m^2) group.[6] However, despite more frequent episodes of febrile neutropenia, intravenous antibiotic use, and hospitalization with G-CSF plus cyclophosphamide (3-4 g/m^2), Awan *et al*. showed a significantly lower average total cost of mobilization compared to that of a planned G+P approach.[7] Costa *et al*. compared a G+JIT approach to cyclophosphamide (2 g/m^2) plus G-CSF and granulocyte-macrophage colony-stimulating factor and showed that the estimated average cost per patient successfully completing mobilization was lower in the G+JIT cohort than in the chemotherapy cohort.[14] Another limitation to the efficacy analysis was a selection bias on the type of patients selected given the lack of randomized comparisons.

In conclusion, this large prospective, observational study showed that overall success of three mobilization regimens is similar with no impact on AHCT outcomes. The resource utilization in chemomobilization was highest among the groups, with outpatient costs being the major contributor of the total costs.

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Disclosures

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Contributions

MH, PH, LJB, and BD conceived the study. MJZ, XT, CM, and LWM performed the statistical analysis. AN, ES, IM, JM, LC, MJ, NS, RC, SU, SF, TN, VR, AB, YB, and ED provided data and critically reviewed the manuscript. BD wrote the first draft, and all authors approved the final version.

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Data-sharing statement

CIBMTR supports accessibility of research in accord with the National Institutes of Health (NIH) data-sharing policy and the National Cancer Institute (NCI) Cancer Moonshot public access and data-sharing policy. The CIBMTR only releases de-identified datasets that comply with all relevant global regulations regarding privacy and confidentiality.

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