Stem Cell Mobilisation Failure in Auto HSCT and Its Factors: A Single Centre Experience

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ABSTRACT

Objective: To determine the mobilisation failure rate and identify its associated factors in this part of the world in order to identify patients at risk of mobilisation failure and to promptly explore alternative treatment.

Study Design: A descriptive study.

Place and Duration of the Study: Department of Clinical Haematology, The Armed Forces Bone Marrow Transplant Centre, Rawalpindi, Pakistan, from January 2014 to July 2023.

Methodology: Clinical records of 115 patients due for autologous haematopoietic stem cell transplantation (auto HSCT) and undergoing mobilisation regimen were analysed. Poor mobilisers were defined as patients who failed to achieve minimum PBSC collection of CD34 >2 x 10^6/kg of recipient body-weight or required an additional dose of Plerixafor after Cyclophosphamide GCSF mobilisation to achieve the target dose.

Results: Among the mobilisation regimes, 85 (74%) were mobilised with Cyclophosphamide followed by GCSF (Cyclo-G), 28 (24%) with GCSF and Plerixafor (G-Plerixafor), and only 2 (2%) with GCSF alone. After the first mobilisation regimen, 84% of patients achieved PBSC collection of CD34 count of >2 x 10^6/kg. The entire mobilisation failure rate was 16%. Successful stem cell collection was significantly correlated with age, lymphoma group and its transplant indication, previous chemotherapy lines, exposure to the type of myelotoxic medicines, steady-state CD34 count, and use of Plerixafor. However, at multivariate analysis, only use of Plerixafor was found associated with successful mobilisation.

Conclusion: Plerixafor significantly improved mobilisation regimens' yield and cost-effectiveness by greatly increasing mobilisation success rates, particularly in heavily pre-treated lymphoma patients.

Key Words: *Haematopoietic stem cell mobilisation*, *Plerixafor*, *Lymphoma*, *Multiple myeloma*, *Plasma cell dyscrasias*.

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INTRODUCTION

The most common indications for autologous haematopoietic stem cell transplant (auto HSCT) globally are plasma cell disorders and primary refractory, relapsed or aggressive lymphomas. Auto HSCT remains an important treatment option to achieve depth of response and prolonging disease-free survival and overall survival.[1,2] However, the success of collecting and transplanting stem cells revolves around effective mobilisation into peripheral blood from the bone marrow niche.[3] Mobilisation regimens have been developed to maximise the circulating CD34+ peripheral blood cells that are collected by apheresis, commonly used are granulocyte-colony stimulating factor (GCSF) alone or in adjunct with chemotherapy or with the synergistic agent Plerixafor.[4]

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The purpose is to obtain desired peripheral CD34 positive cells count >2 x 10^6/kg, to guarantee early haematological recovery, and to reduce the duration of hospital stay and neutropenic phase, and the need for blood product.[2,5] One of the biggest challenges in executing auto HSCT is inadequate mobilisation of peripheral blood stem cell (PBSC).[6] Though mobilisation techniques have made significant progress, a large percentage of mobilisation failures (15–30%) still occur.[7] Nonetheless, the effect of several factors on stem cell mobilisation has been identified that includes age, gender, underlying disease, prior lines of treatment, exposure to radiation, bone marrow involvement, and mobilisation strategy.[8]

The aim of this study was to determine the mobilisation failure rate in this part of the world and identify its associated factors in order to identify patients who may be at risk. This would lower the cost of repeat apheresis by choosing a preferred mobilisation regimen and promptly exploring alternative treatments in the event of mobilisation failure.

METHODOLOGY

This descriptive cohort study was retrospectively performed. The clinical records of 115 patients who underwent peripheral stem cell mobilisation and PBSC (apheresis) collection from

January 2014 to July 2023 at the Armed Forces Bone Marrow Transplant Centre, Rawalpindi, Pakistan, were reviewed. Clinical records of the patients were reviewed and data were collected through non-probability convenience sampling technique. This study included patients of all age groups, genders, and diseases that underwent stem cell mobilisation with any regimen prior to auto HSCT. However, allogeneic PBSC donors and patients who failed to complete mobilisation regimen due to any reason were excluded.

Effective stem cell mobilisation was defined as PBSC collection of CD34 >2 x 10^6/kg of recipient body weight.[9] Poor mobilisers are defined as patients who failed to achieve above-defined minimum CD34 count or required an additional dose of Plerixafor after Cyclophosphamide GCSF mobilisation to achieve the target dose.[8,10,11]

Data were analysed through SPSS version 25. In the descriptive analysis, percentage and frequency were calculated for categorical variables and mean ± standard deviation or median and interquartile range (IQR) for all the continuous variables. In univariable analysis, the chi-square test was applied to look for an association of the outcomes of mobilisation with the subsequent factors I-e: Age, gender, type and stage of disease, previous lines and number of cycles of chemotherapy, disease remission status, serum ferritin, exposure to myelotoxic agents, type of mobilisation regimen, and blood counts (WBC, Hb Plts) at the start of mobilisation and at the day of first apheresis. For continuous variables, the authors applied Spearman's correlation test to find a correlation with PBSC collected CD34 count. The confidence interval of 95% and p-value of 0.05 were considered statistically significant. In multivariate analysis, the authors applied logistic regression to check the odd ratio of significant variables.

RESULTS

The study cohort included 115 patients with a mean age of 42±14.9 years undergoing stem cell mobilisation for lymphomas 49 (43%), plasma cell disorders 64 (56%), and non-haematological disorders 2 (1%) that included multiple sclerosis and clear cell sarcoma of the kidney. Patients with plasma cell disorders had multiple myeloma 59 (92%), POEMS syndrome 4 (6%), and one (1%) case each of plasma cell leukaemia and renal amyloidosis. The mean days of GCSF administration were 5 (IQR: 5-6). Steady-state CD34 count was performed for 61 patients with a mean steady-state CD34 count of 11.0 /ul (IQR: 2.5-17.5). Three types of mobilisation regimens were used, among which 85 (74%) Cyclophosphamide followed by GCSF (Cyclo-G), 28 (24%) GCSF and Plerixafor (G- Plerixafor), and only 2 (2%) with GCSF alone. Median sessions of apheresis for PBSC were 2 (IQR: 1-2). PBSC collection of CD34 count of >2 x 106/kg was achieved in 96 (84%) after the first mobilisation regimen, among which 6 patients required >3PBSC sessions to achieve the target dose. With the first mobilisation regimen, the overall failure rate of mobilisation was 16% (n = 19). Of these, 17 (25%) of Cyclo-G regimen failed, 2 (7.6%) of G- Plerixafor, and none of GCSF alone. Twelve patients (10%) were given an additional dose of Plerixafor following Cyclo-G mobilisation, and 6 patients (4%) got successful in meeting the target. The remaining 13 poor mobilisers (11%) received a second mobilisation regimen CycloG 2 (15%), G-Plerixafor 11 (85%). However, 3 (2%) patients failed to mobilise even after 2nd mobilisation regimen and underwent allogeneic HSCT.

Twenty-eight (57%) Hodgkin's and 21 (43%) non-Hodgkin lymphoma patients were included in the study. Before mobilisation, the mean WBC was 5.5 x 10^9/l (IQR: 4.3-7.35), Hb was 12.3g/dl (IQR: 11.2-13.8), and platelets were 211 x10^9/l (IQR: 168-262). Post-mobilisation median blood counts were WBC 15.4 x 10^9/l (IQR: 10.4-24.9), Hb 11.4 g/dl (IQR: 10.3-12.6), platelets 156 x 10^9/l (IQR: 103-191). By using Wilcoxon-signed rank test, a significant difference was observed in pre-and post-mobilisation blood counts.

Age, diagnosis, transplant indication in lymphoma, prior lines of chemotherapy, disease remission status at transplant, exposure and type to myelotoxic agents, steady-state CD34 count, and use of Plerixafor had significant association with successful stem cell collection (Table I). By using Spearman's correlation test, CD34 count had a weak correlation with post-mobilisation blood counts. However, WBC ($r = 0.18$, $p = 0.05$) and Hb ($r = 0.18$, $p = 0.05$) showed a positive correlation. On the other hand, CD34 count and platelets showed a negative correlation ($r = -0.03$, $p = 0.97$). Likewise, there was a weak negative correlation between the serum ferritin and the PBSC collection ($r = -0.09$, $p = 0.321$). A one-day increase in the time from diagnosis to mobilisation decreased the CD34 counts ($r = -0.25$, $p = 0.006$). In the multiple myeloma group, there was a weak, non-significant correlation between the number of chemotherapy cycles and successful mobilisation. With each additional chemotherapy cycle, CD34 counts decreased ($r = -0.15$, $p = 0.09$).

However, in multivariate analysis, it was found that using Plerixafor either upfront or in addition to Cyclo-G increased the likelihood of successful mobilisation by 83% (Table II).

DISCUSSION

Adequate peripheral blood stem cell collection is the central core of auto HSCT, thus failure to mobilise is a significant problem owing to lesser treatment modalities available afterwards. Achieving an effective CD34 count with optimal resources and few complications is the goal of mobilisation. The effectiveness of stem cell mobilisation dictates the number of apheresis procedures required and the outcome of transplantation in terms of blood count engraftment. Successful mobilisation was positively connected with younger age, plasma cell dyscrasia, fewer previous treatment lines, lesser exposure to myelotoxic agents, use of Plerixafor in the mobilisation regimen, and greater steady-state CD34 levels. The majority of patients were successfully mobilised using two apheresis procedures, with an overall mobilisation failure rate of 16%. The expected prevalence of mobilisation failure ranges from 6 to 23%, through it is not entirely known due to different criteria used.[10,12]

Table I: Factors affecting stem cell mobilisation.

Factor studied	Total n (%)	Good mobilisers n (%)	Poor mobilisers n (%)	p-value
Age groups	Children 8 (7%)	4 (50%)	4 (50%)	0.008
	Adults 107 (93%)	92 (86%)	15 (14%)	-
Gender	Male 83 (72%)	70 (84%)	13 (16%)	0.69
	Female 32 (28%)	26 (81%)	6 (19%)	-
Disease	Lymphomas 49 (43%)	32 (65%)	17 (35%)	<0.001
	Plasma cell disorders 64 (56%)	62 (97%)	2 (3%)	-
	Non-haematological disorders 2 (1%)	2 (100%)	0 (0%)	-
MM subtypes	IgG 25 (42%)	24 (96%)	1 (4%)	0.879
	IgA 12 (20%)	11 (92%)	1 (8%)	-
	Light chain myeloma 5 (9%)	5 (100%)	0 (0%)	-
	Non-secretory 8 (14%)	8 (100%)	0 (0%)	-
	Missing 9 (15%)	9 (100%)	0 (0%)	-
Types of lymphomas	Hodgkin's disease 28 (57%)	16 (57%)	12 (43%)	0.166
	NHL 21 (43%)	16 (76%)	5 (24%)	-
Transplant indication for lymphoma	Upfront 11 (22%)	11 (100%)	0 (0%)	<0.001
	Primary refractory 17 (35%)	12 (71%)	5 (29%)	-
	Relapse 21 (43%)	9 (43%)	12 (57%)	-
MM stage at diagnosis	ISS I 21 (36%)	20 (95%)	1 (5%)	0.494
	ISS II 16 (28%)	16 (100%)	0 (0%)	-
	ISS III 13 (22%)	13 (100%)	0 (0%)	-
Lymphoma stage at diagnosis	Low risk 17 (35%)	10 (58%)	7 (41%)	0.487
	High risk 32 (65%)	22 (68%)	10 (31%)	-
Lymphoma disease status at mobilisation	CMR lymphoma 46 (94%)	29 (63%)	17 (37%)	0.193
	PR lymphoma 3 (6%)	3 (100%)	0 (0%)	-
MM disease status at mobilisation	sCR MM 30 (50%)	28 (93%)	2 (7%)	0.558
	CR MM 26 (44%)	26 (100%)	0 (0%)	-
	PR MM 2 (3%)	2 (100%)	0 (0%)	-
	VGPR 2 (3%)	2 (100%)	0 (0%)	-
Prior lines of treatments	<3 Lines of chemotherapy 79 (69%)	75 (95%)	4 (5%)	<0.001
	>3 Lines of chemotherapy 36 (31%)	21 (58%)	15 (42%)	-
Exposure to myelotoxic agents	Yes 88 (77%)	70 (80%)	18 (20%)	0.040
	No 27 (23%)	26 (96%)	1 (4%)	-
Type of myelotoxic agent	No exposure 27 (23%)	26 (96%)	1 (4%)	<0.001
	Radiotherapy alone 1 (1%)	1 (100%)	0 (0%)	-
	Platinum compounds 32 (28%)	18 (56%)	14 (44%)	-
	Lenalidomide 44 (38%)	42 (96%)	2 (4%)	-
	Others (MTX, Fludarabine) 2 (2%)	2 (100%)	0 (0%)	-
	Multiple agents used other than radiotherapy 9 (8%)	7 (78%)	2 (22%)	-
Exposure to radiotherapy	No 95 (83%)	81 (85%)	14 (15%)	0.261
	Yes 20 (17%)	15 (75%)	5 (25%)	-
1st MR	-	-	-	-
Cyclo-G	Lymphoma 39 (46%)	24 (80%)	15 (20%)	0.231
	Plasma cell disorders 45 (54%)	43 (96%)	2 (4%)	-
G-Plerixafor	Lymphoma 10 (37%)	8 (93%)	2 (7%)	-
	Plasma cell disorders 17 (63%)	17 (0%)	0 (0%)	-
GCSF only	Plasma cell disorders 2	2 (100%)	0 (0%)	-
Steady-state CD34	>10/ul 33 (54%)	33 (100%)	0 (0%)	<0.001
	<10/ul 28 (46%)	19 (68%)	9 (32%)	-
PBSC-c sessions	<3 session 100 (87%)	90 (90%)	10 (10%)	-
	3 or more sessions 15 (13%)	6 (40%)	9 (60%)	-
Use of plerixafor	Yes 40 (35%)	26 (65%)	14 (35%)	<0.001
	No 75 (65%)	70 (93%)	5 (7%)	-

MM: Multiple myeloma, ISS: International scoring system, CMR: Complete metabolic remission, sCR: Stringent complete remission, CR: Complete remission, PR: Partial remission, VGPR: Very good partial remission, MR: Mobilisation regimen, PBSC-C: Peripheral blood stem cell collection. Univariate analysis by Chi-square.

Table II: Multivariate analysis of significant variables.

Factors		Crude odd ratio	95% CI		p-value	Adjusted OR	95% CI		p-value
			LL	UL			LL	UL	
Use of plerixafor	Yes	0.13	0.04	0.41	**<0.001**	0.175	0.040	0.785	**0.023**
Age	Children	6.13	1.38	27.2	**0.02**	3.54	0.52	23.96	0.195
Gender	Female	1.24	0.43	3.61	0.69				
Diagnosis					**0.002**				>0.99
	PCD	0.06	0.01	0.28	**<0.001**	0	0	.	0.998
Transplant indication					**<0.001**				0.369
	Upfront	0.02	0.01	0.13	<0.001	0	0	.	0.999
	Pri-ref.	0.38	0.10	1.44	0.16	0.31	0.06	1.575	0.158
Type of myelotoxic agent					**0.004**				0.417
	No exp.	0.13	0.01	1.71	0.122	0.044	0.002	1.119	0.059
	Radiotherapy only	0	0	.	1.00	0.231	0	.	>0.99
	Platinum compounds	2.72	0.49	15.1	0.254	0.475	0.036	6.312	0.572
	Lena	0.16	0.02	1.38	0.097	17796150	0	.	0.998
	Others (MTX, Flu)	0	0	.	0.999	0	0	.	0.999

LL: Lower limit; UL: Upper limit; OR: Odds ratio; PCD: Plasma cell disorders; Pri-Ref: Primary refractory; Exp: Exposure; Lena: Lenalidomide; MTX: Methotrexate; Flu: Fludarabine.

Johnsrud *et al*. had comparable rates of effective stem cell collection and engraftment time with Cy GCSF and GCSF with Plerixafor,[1] and similar findings were observed in this study. Nonetheless, similar to other earlier studies that evaluated the cost-effectiveness of Plerixafor, this study also ascertained the use of Plerixafor, either upfront or in addition to Cyclo-G, significantly increases the chance of successful PBSC collection, hence reduces the number of apheresis days.[13,14]

These findings also provide compelling evidence for the previously established function of steady-state CD34 in patients undergoing mobilisation, suggesting that peripheral CD34 by flow cytometry is the best predictor for starting stem cell collection.[15]

Furthermore, it was found that the disease had a substantial impact on the success rate of PBSC collection; mobilisation failure rates were ten times higher in the lymphoma group, in contrast to patients with plasma cell dyscrasia, probably due to the impact of prior high-dose chemotherapy administered to lymphoma patients compared to those with multiple myeloma.[10] In a similar vein, worse mobilisation outcomes in lymphoma were significantly linked with exposure to multiple lines of chemotherapy and myelotoxic medicines. This finding was also concluded by a multicentre study in Germany and Australia.[16,17] The increased mobilisation failures are explicable by a greater usage of multiple lines in the therapy of lymphoma. However, contrary to other studies, radiotherapy alone was not significant to cause mobilisation failure in any group.[18] Overall, mobilisation rate was better in plasma cell disorders and no single factor was found significantly associated with failure in this group.[19] Compared, to other studies, there was a weak correlation between age and the number of CD34+ cells collected. However, due to the small number of children in the cohort, a substantial prediction of mobilisation and its factors in children was not possible. When compared to other studies[20] that found similar results, the observation of elevated serum ferritin in the poor mobilisers group was not statistically significant. Additionally, in this analysis, the interval between diagnosis and successful PBSC collection was negatively correlated akin to other studies.[19]

Several limitations of this analysis included single-centre study, retrospective design, and inclusion of lymphoma and myeloma patients together. Further randomised control trials and multicentre studies should be conducted in this part of the world to correctly identify the risk of mobilisation failure and its impact on engraftment and to conclude any difference between ethnic origins. Studies are required to evaluate other mobilisation regimens and further optimisation in poor mobilisers, especially in lymphoma patients.

CONCLUSION

Mobilisation should be considered early in the course of treatment whenever possible, since patients with extensively pre-treated lymphoma, especially those exposed to myelotoxic agents, are difficult to mobilise with a single mobilisation strategy. While–most but not all–of these patients can get benefit from Plerixafor. Also, steady-state CD34 is an excellent predictor of mobilisation failure.

ETHICAL APPROVAL:
Ethical approval was received from the Institutional Review Board of the Armed Forces Bone Marrow Transplant Centre under the IRB Number: 016/BMTC/R&P, dated: 20/11/2021

PATIENTS' CONSENT:
The study participants and/or their relatives provided their voluntary agreement and approval for the use of the data.

COMPETING INTEREST:
The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:
IH: Conception, design of the work, and data interpretation.
MAK: Design of the work.
MNA: Data acquisition, critical reviewing, and manuscript editing.
AS, SR, QU: Data Collection and statistical evaluations.
All authors approved the final version of the manuscript to be published.

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