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Comparison of Efficacy and Safety of Generic Plerixafor Vs Original Plerixafor in the Mobilization of Myeloma Patients

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Abstract Introduction
The commonest indication for an Autologous Stem Cell Transplantation (ASCT) is still Multiple Myeloma. A successful mobilization of hematopoietic stem cells (HSC) is a sine qua non of ASCT. The introduction of Plerixafor, which is a partial agonist of the alfa-chemokine receptor CXCR4 has added an important value and impact on mobilization. Plerixafor is successfully integrated into both growth factor-only and cyclophosphamide and growth factor mobilization strategies with significantly reducing the mobilization failure rate in myeloma patients. In addition, plerixafor + G-CSF has also been shown to successfully mobilize the majority of patients who previously failed to mobilize with either growth factor alone or in combination with chemotherapy. Even a Just-in-Time algorithm which induces plerixafor in patients who lacks a certain threshold of CD34 positive HSCs on the day of mobilization led to a cost-effective and successful mobilization with highly restricted rates of mobilization failure.
In this study we tried to demonstrate the efficacy and safety of a novel generic Plerixafor (Pleksor - Gen Ilac) and to compare it with original one (Mozobil - Sanofi) in a retrospective manner.
Method Patients who were transplanted in two centers who adopted the same mobilization standard operating procedures (SOP) were included in the study. An age and sex matched cohort of patients who received Mozobil (from 2020-2022 - Group A) were compared with the ones who received Pleksor (2021-2022 Group B) as a Just-in-Time conjunct to GCSF alone or chemo mobilization. Poor mobilization was defined as a final yield of 2 million CD34 positive HSCs per kg. Our aim was to collect enough stem cells for at least two ASCTs, thus our current SOP's indicated a minimum CD34 positive HSC threshold of at least 4 million per kg and an ideal HSC threshold of 6 million per kg.
Results
A total of 28 patients were included and they were equally distributed among Group A (n=14) and B (n=14). Median age of the patients at the time of mobilization were as follows, 60 (35-72) in Group A and 61 (38-70) in Group B. 14 patients who received Pleksor achieved a median yield of 8.40 million CD34 positive HSCs per kg (4.8-21) and the patients who received Mozobil have ended with a yield of 6.7 million CD34 positive HSCs per kg (4.5-13) (p=0.210). None of the patients in both groups were named to be a poor mobilizer according to the threshold of 2 million CD34 positive HSCs per kg but 3 of the patients in Group A and 2 of the patients in Group B ended with a yield of 6 million CD34 positive cells which was below to the ideal threshold for two transplants. Regarding lenalidomide exposure before mobilization, history of radiotherapy, line of the therapies received before mobilization, number of leukapheresis and the mobilization policy (chemo vs gcsf alone) there were no statistically significant difference between two groups (p=0.120, 0.702, 0.842, 0.769 and 0.420 respectively). The median

neutrophil engraftment time in days were as follows for Group A and B, 11(10-14) vs 11 (10-16), p=0.541 and the median platelet engraftment time in days were 17 (10-30) in Group A and 16 (10-28) in Group B with a p value of 0.571. In none of the cases any specific side effects were noted which could be attributable to Pleksor or Mozobil.

Conclusion Our study demonstrated a comparable efficacy of a generic form of Plerixafor when compared with the originator. This would lead to a decrease in the cost of total process of mobilization with a similar efficacy and toxicity profile. We are now planning to initiate a prospective trial to validate these results in a larger patient population. Up to our knowledge this is the first study comparing the efficacy of a generic Plerixafor in a sole myeloma patient cohort.

Disclosures No relevant conflicts of interest to declare.

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