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Comparison between bio-similar filgrastim vs. other G-CSF formulations (originator filgrastim, peg-filgrastim and lenograstim) after autologous stem cell transplantation: A retrospective survey from the Rome Transplant Network

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Only limited data have been so far published about the use of biosimilar filgrastim in hematologic recovery after ASCT. The aim of this study was to compare the biosimilar filgrastim Zarzio® with the other available formulations of G-CSF in terms of efficacy and safety. From March 2013 to June 2014 we used in our Institution biosimilar filgrastim (Zarzio®, Sandoz Industrial Products Spa, Rovereto, Italy) at dosage of 5 mcg/Kg daily given from day 3 after stem cell infusion for febrile neutropenia prophylaxis and hematologic recovery in 64 consecutive adult patients who underwent ASCT. These patients were retrospectively compared with three historical cohorts: a) 99 consecutive adult patients treated with lenograstim (Myelostim®, Italfarmaco Spa, Milano, Italy) at same dosage and timing in our Institution from January 2009 to February 2013; b) 60 consecutive adult patients treated with peg-filgrastim (Neulasta®, Amgen Spa, Milano, Italy) at dosage of 6 mg single dose at day 3 after stem cell infusion in our Institution from March 2006 to December 2008; c) 79 consecutive adult patients treated with originator filgrastim (Granulokine®, Amgen Spa, Milano, Italy) at dosage of 5 mcg/Kg daily given from day 3 after stem cell infusion in Hematology Unit of Campus Bio-Medico University from May 2008 to June 2014. There is not any statistically significant difference among the four patient cohorts. We analyzed the time of hematologic recovery after stem cell infusion (defined as an absolute neutrophilis count upper than 0.5 x 109/L and a platelets count upper than 20 x 109/L), the occurrence of fever of unknown origin (FUO) in neutropenia, documented infectious episodes and needing of intravenous antibiotic treatment, the number of red blood and platelet transfusions, the days of hospitalization and the transplant-related mortality (TRM). We observed a significantly shorter time to neutrophilis and platelet recovery (P=0.016 and P=0.007, respectively) with a consequent lower median number of platelet transfusions (P=0.016) in the cohort of patients treated with Neulasta®, whereas no difference was observed among the other three groups. Moreover, we did not observe any significant difference among the four patient cohorts for all the other analyzed parameters. No difference in terms of drug-related adverse events was observed in the four patient cohorts with no serious adverse events. Considering the median days of G-CSF injections and assuming a patient median body weight of 60 Kg, the estimated cost for each patient was significantly lower in the Zarzio® group (approximately 73€) when compared with the other groups (approximately 732€ for Myelostim®, 649€ for Granulokine® and 660€ for Neulasta®; P<0.0016). Biosimilar filgrastim (Zarzio®) seems to be substantially equivalent in terms of efficacy and safety to the other G-CSF formulations when used for febrile neutropenia prophylaxis and hematologic recovery after ASCT. However, the use of biosimilar filgrastim consents to significantly limit the costs in this setting of utilization. Further prospective randomized studies are warrant to confirm these results.

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