P1362 FEASIBILITY OF HAEMATOPOIETIC STEM CELL MOBILIZATION AFTER CONSOLIDATION WITH GEMTUZUMAB OZOGAMICIN AND INTERMEDIATE-DOSES ARA-C AND DAUNORUBICIN IN AML

Topic: 22. Stem cell transplantation - Clinical

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Background:

Gemtuzumab ozogamicin (GO), an anti-CD33 immunoconjugate Antibody is currently approved in combination with 7 + 3 in low- and intermediate risk acute myeloid leukaemia (AML). These patients are candidate for consolidation with autologous stem cell transplantation (ASCT) particularly when MRD- is obtained. GO can improve the rate of MRD negativity. There are limited data on the effect of its addition on the mobilization of Hemopoietic Stem Cells (HSC).

Aims:

To assess the feasibility of mobilization of HSC after re-introduction into market of GO at 3mg/m² in 2019.

Methods:

We retrospectively studied AML patients undergoing 3+7 + GO induction and Ara-C + Daunorubicine + GO, consolidation (doses are derived from label instructions and ALFA0701 study) and mobilization on day +20 using G-CSF 10µg/kg. CD34+ were monitored, and patients were harvested when a threshold of 20 cells/µL was reached in peripheral blood.

Results:

In 2020 and 2021, also considering constrains caused by COVID-19 pandemics, we attempted mobilization in our 3 Italian centres of 14 patients with a diagnosis of CD33+ de novo-AML. The median age was 52 years (range 29-65 yrs.), 4 were males and 10 females; 11 patients carried a mutation of NPM1 and all had a normal karyotype except one with t(10p12;11q14) (Table 1). All received 3+7+GO induction and achieved a CR. Therefore, we started consolidation (total ARA-C 8g/m²) + GO as inpatient.

Ten patients (71%) reached the established threshold of 20 CD34+ /µL and were successfully harvested, while 4 patients (29%) failed mobilization. The median number of circulating CD34+ cells on the day of collection was 35.9 cells/µL (range 20-2153 cells/µL). The median CD34+ harvested was 4.65 x 10⁶/kg (range 1.8- 44.6 x 10⁶/kg). In our cohort, 4 patients (28% of the entire cohort and 40% of the harvested patients) underwent ASCT, 3 achieved favourable engraftment, while in the last patient ASCT is ongoing. Several reasons prevented ASCT in the remaining 6 patients: 3 patients underwent allogeneic SCT (2 had positive MRD on harvested apheresis; 1 was reclassified as high-risk ELN2017 due to RUNX1 mutation resulting from NGS panel), 2 refused ASCT and one suffered early relapse.

Image:

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Summary/Conclusion:

In our patients, the addition of GO did not impair HSC mobilization and harvesting that was reached in about 71% of cases, similarly to the AML-10 trial of the EORTC and GIMEMA Leukemia Groups where 70% of patients were successfully harvested.

Our data are particularly interesting because in the pivotal ALFA0701 study, only one patient underwent Autologous-SCT, but in the control arm. An important limit of our case-series is that only 4 patients were auto-transplanted, so we have scant data on engraftment. In particular, evaluating day to engraftment of platelets would be interesting, given the known increase of thrombocytopenia in patients treated with GO. In conclusion, mobilization with GO is feasible and further studies are warranted to evaluate the effects of fractioned doses of GO on HSC mobilization and ASCT outcome; the ongoing trial GIMEMA AML1819 - EudraCT number 2019-003871-20 - will prospectively assess the effect of GO, but with lower doses of ARA-C (total ARA-C 6 g/m²).