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Editorial and Comments

Effects of Daratumumab on Hematopoietic Stem Cells in Patients with Multiple Myeloma Who Are Planned to Receive Autologous Transplantation: What's the Relevance?

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Induction combo therapies, including the humanized anti-CD38 monoclonal antibody daratumumab, followed by CD34+ hematopoietic stem cells (HSCs) collection and autologous stem cell transplantation (ASCT), represent the current standard of care for the initial treatment of transplant eligible patients with newly diagnosed multiple myeloma (TE-NDMM).[1] However, evidence from the pivotal randomized phase 3 CASSIOPEIA trial[2,3] firstly suggested that daratumumab added to bortezomib, thalidomide, and dexamethasone (D-VTd) may also negatively influence CD34+ HSCs mobilization in peripheral blood and post-ASCT engraftment respect to VTd alone. Along with several other studies (that will be summarized further ahead in this editorial), two papers recently published in the Mediterranean Journal of Hematology andInfectious Diseases (MJHID) have covered this topic in a real-world setting.[4,5]

Cavallaro et al.[4] reported a comparison between 109 TE-NDMM patients receiving induction therapy with D-VTd and 100 similar patients treated with VTd from January 2022 to June 2023 in 4 Italian hematologic centers. Most patients received the four planned cycles (106/109 in the D-VTd group vs 89/100 in the VTd group, respectively). Mobilizing therapy consisted of cyclophosphamide (CTX) (1-3 gr/sqm) followed by granulocyte colony-stimulating factor (G-CSF) or only G-CSF if age was greater than 70 years or in the presence of renal impairment (eGFR < 50 ml/min). The median number of CD34+ HSCs collected was significantly lower with D-VTd (5.2 x 10^6/Kg) than with VTd (9.0 x 10^6/kg) ($p < 0.0001$) and D-VTd treated patients also required a greater use of plerixafor (PLX) (49.5% vs 10% in those receiving VTd). Two patients (1.8%) failed HSCs mobilization in the D-VTd arm, whereas no mobilization failure was registered with VTd. At data cut-off, the first ASCT was performed in 100/107 D-VTd patients (six patients were still waiting for the procedure, and one patient experienced disease progression after the HSC harvest). Three out of the 100 VTd patients did not undergo ASCT because of medical decision. Patients receiving D-VTd also showed a slower median time to neutrophils (PMNs) and platelets (PLTs) engraftment (13 vs 11 days in both cases, $p< 0.0001$); however, no differences were reported in terms of infection incidence between the two arms.

Passucci et al.[5] described instead a single-center comparison between 36 (arm A) and 43 (arm B) TE-NDMM patients treated with D-VTd or VTd, respectively, between 2020 and 2023. All patients received an intermediate dose of CTX (2.4 gr/sqm) followed by G-CSF; based on the evidence of poor

harvesting, the CTX dose was increased to 3.0 gr/sqm in arm A in October 2022. At the first attempt, the median number of CD34+ HSCs collected was not significantly different between the two groups (8.6 vs 9.1 x 10^6/kg in arm A and arm B, respectively, p = 0.4), however a greater number of patients in D-VTd arm (8/36, 22%, versus 6/43, 14% with VTd) required PLX. Three patients failed HSCs mobilization in the D-VTd group, whereas no mobilization failure was reported in arm B. After a median follow-up of 21.2 months, 64% of patients in Arm A and 91% of those in arm B had received at least one ASCT. The median time of engraftment was significantly longer in arm A, both for PMNs (11.0 vs. 10.0 days, p= 0.03) and PLTs (15.0 vs. 14.0 days, p=0.008), but no differences emerged interms of infections requiring multiple antibiotics and median days of hospitalization.

The effects of prior daratumumab exposure on HSCs harvesting and engraftment in TE-NDMM were recently reported in a meta-analysis of 5 published studies conducted between 2015 and 2020.[6] PLX was used in all but one of these studies. A high heterogeneity in sample characteristics and collection methods was observed, and several publication biases were reported. Overall, a reduced amount of collected HSCs was observed with daratumumab, but this did not result in the failure of collection, as the minimal threshold of 2×10^6/kg HSCs was collected in all studies, while the result of 4×10^6/kg still varied. However, the use of PLX to help patients receiving daratumumab to collect enough stem cells clearly might skew results. The effects of daratumumab on hematopoietic reconstitution were investigated in 4 studies. Globally, daratumumab did not affect the time to PMN engraftment. Still, it had a certain negative effecton PLT reconstitution, with a marginally longer numberof days required for their recovery. The authors concluded that daratumumab doesn't seem to harm HSCs number or health when patients are prepared for collection in the best possible way.

More recently, Bigi et al. published a detailed systematic review of the impact of anti-CD38 monoclonal antibody therapy on CD34+ HSCs mobilization, collection, and engraftment in patients with TE-NDMM.[7] These authors analyzed 26 reports published between 2019 and 2024, including both clinical trials and real-life studies. Most of them focused on daratumumab, but, despite fewer experiences, isatuximab appeared to exhibit similar trends in terms of HSC mobilization. The large majority of studies reported lower levels of circulating CD34+ HSCs in the peripheral blood of patients treated with anti-CD38 antibodies after mobilization compared to controls, leading to a more frequent use of PLX. The total amount of CD34+ HSCs collected was also significantly inferior to the control groups in approximately half of the controlled studies. However, the collection target was reached in a similar proportion of patients, and those treated with daratumumab or isatuximab had comparable access to ASCT. This was explained by the possible retained efficacy of PLX in patients receiving anti-CD38 monoclonal antibodies, while no chemotherapy-based or sparing mobilization protocol was superior. About half of the studies also reported slower hematopoietic reconstitution after ASCT in daratumumab or isatuximab-treated patients in terms of both PMN and PLT recovery. However, in most studies, the delayed PMN engraftment did not lead to an increased rate of infectious complications. Prolonged daratumumab exposure (more than 4-6 induction cycles) and its delayed clearance were associated with reduced collection efficiency. The daratumumab-free intervaldid not impact HSCs mobilization and collection. Regarding the optimal mobilization strategy to apply when anti-CD38 antibodies are used, there were nostandardized approaches, and different institutionspreferred variable chemo-free or chemo-including strategies based on their usual clinical practice and PLXavailability.

In an updated real-life experience, only partially reported in the previous review, 78 consecutive patients with TE-NDMM received induction therapy with D-VTd, followed by stem cell mobilization therapy between November 2021 and March 2023 at 12 Italian Centers.[8] Ninety-two percent of patients underwent 4 cycles of induction therapy. Mobilization of HSCs in peripheral blood was induced with a combination of CTX with G-CSF in 70 patients (90%). Three patients (4%) received G-CSF alone; one patient (1%) received G-CSF plus plerixafor, and 4 patients (5%) received CTX plus G-CSF and plerixafor. Analyzing the possible impact of the inclusion of daratumumab into induction therapy, 73/78 patients (93%) met the collection goal after mobilization therapy. Nevertheless, 5 (7%) and 2 (3%) out of these patients required a second and third mobilization attempt, respectively. Moreover, 5 out of 78 patients (6%) failed HSC collection at all. The median number of CD34+ HSCs collection yield for the entire cohort was 7.6×10^6 cells/Kg. The median time between the last day of induction therapy and the first day of mobilization therapy was 31 days. Overall, PLX on demand was administered in 24/78 patients (30%), failing to achieve the desired collection goals, thus confirming that a larger use of this drug was necessary, compared to the prior experience of the centers based on VTd induction therapy. Besides the use of daratumumab, baseline plasmacytoma was associated with a lower rate of collection goal, while the number of induction cycles, depth of response at the time of apheresis, and type of mobilization therapy did not. Patients with lower pre-mobilization therapy levels of PMNs showed a significantly reduced collection goal after the first mobilization attempt, possibly due to prolonged hematological toxicity after induction therapy.

Lastly, our group recently led the retrospective, case-control PRIMULA study to evaluate the impact of daratumumab on peripheral CD34+HSCs mobilization, collection, and post-transplant engraftment in a real-world setting.[9] This study was conducted across 14 Italian centers by comparing 151 TE-NDMM patients receiving D-VTd as induction therapy from February 2022 to July 2023 to a historical control cohort of 64 patients previously treated with VTd alone. Patientswere matched for age, ISS, number of induction cycles,and HSC mobilization strategies. Overall, the median number of CD34+ HSCs collected was significantly lower in the D-VTd group, compared to VTd (6.7 x 10^6/kg vs 8.2 x 10^6/kg, respectively, p<0.0001). Patients treated with D-VTd also required a higher use of PLX (57% vs 33%, p<0.0001) and more frequentmobilization attempts (15% with 2 attempts versus 6%, p=0.03). Accordingly, more than half of patients in the D-VTd group needed ≥2 apheresis as compared to less than one-third in the VTd cohort (p=0.0005). A statistically significant correlation between the HSCs collected and the days from the last daratumumab administration was also observed. No "proven" poor mobilizers (CD34+x10^6/kg < 2 in 3 apheretic sessions)[10]occurred in the VTd group, while they accounted for 6%in the D-VTd treated patients. The median time to PMNsand PLTs engraftment was one day longer in the D-VTd group compared to VTd (11 vs 10 days, p < 0.0001, and12 vs 11 days, p = 0.0005, respectively). However, all patients in both groups received ASCT, and no difference in grades 3-4 adverse events emerged.

Looking at possible causes through which daratumumab could influence HSC mobilization, some authors hypothesized direct toxicity of the drug.[5] Similar results were observed in vitro with isatuximab.[11] However, the majority of literature data supports alternative mechanisms related to cell adhesion.[12-15] Indeed, daratumumab or isatuximab may affects the bone marrow niche, which is crucial for the support and release of CD34+ HSCs through overexpression of adhesion genes and enhanced adhesion-related interactions, for example, VLA-4/VCAM-1 and CXCR4/CXCL12 axes.[15] These molecules could interfere with the function of stromal cells and other components of the niche, leading to impaired homing and retention of HSCs. The efficacy of PLX demonstrated in this context in enabling satisfactory yields of HSCs for most daratumumab-treated patients would further support such a hypothesis.[16] Prolonged high levels of circulating daratumumab have also been associated with a negative effect on HSC mobilization,[17] while reduced chemotactic properties could potentially explain the observed delay in hematopoietic reconstitution after ASCT.

Obviously, other possible factors associated with poor HSC mobilization should be taken into account. Among these are age, baseline marrow infiltration or cytopenia, hematological toxicity developed during induction with the use of further agents combined with anti-CD38 antibodies (in particular alkylating chemotherapy and lenalidomide), exposure to radiotherapy, and priming strategies with G-CSF alone or without upfront plerixafor.[3,6,18-20]

Conclusions. The integration of daratumumab into the treatment landscape for TE-NDMM has raised some concerns about its potential to induce a lower collection of CD34+ HSCs, a higher number of poor mobilizers and apheresis procedures, a longer time to PMNs and PLTs engraftment and an increased need for the rescue use of plerixafor. The same concerns could likely occur with isatuximab once the drug is approved for frontline use. Notwithstanding, interference with releases from the bone marrow of HSCs generally does not have clinically significant consequences, as most patients treated with daratumumab have regular access to a safe ASCT, being only rarely reported, for example, higher transfusion requirements or infectious complications.[21] This evidence, however, mostly derives from small studies with the variability of induction therapies, mobilization strategies, and collection targets. This makes it difficult to compare published reports, allowing, so far, only a narrative evaluation. At the same time, the optimal mobilization strategy for patients treated with anti-CD38 monoclonal antibodies still needs to be defined. Cost-effectiveness is also a relevant point. Despite transplant feasibility and safety appear generally not compromised by daratumumab, a larger need for PLX and leukapheresis procedures, as well as a possible longer hospitalization, may determine higher expenses, with a not negligible impact on financial resources and the need for appropriate cost analysis, not available so far. Thus, given the continued need for ASCT and the challenges posed by anti-CD38 monoclonal antibodies, it would be necessary to develop individualized HSC mobilization strategies with algorithms based on all interfering factors, therapeutic objectives, and locally established practices. This is particularly necessary for selected patients where double ASCT strategies, with a higher number of HSCs required, should still be considered (i.e., ultra-high risk MM and primary plasma cell leukemia).

That said, it is clear that the outstanding benefits of anti-CD38 monoclonal antibodies largely overcome the possible impact on HSCs-related outcomes, and their use in clinical practice must be maintained. Newer induction therapies involving daratumumab or isatuximab-based quadruplets have recently been shown to provide superior outcomes in terms of response and progression-free survival, which hopefully will translate into a survival advantage.[22–24] Further investigations are therefore warranted to identify the best mobilization strategy(es) for these patients.

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