PP 35

Pomalidomide-dexamethasone in the management of heavily pretreated multiple myeloma

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Objective: Pomalidomide is a new generation IMID, with a very good compliance, thanks to oral administration, which can be used also in heavily pretreated patients, in a domestic setting.

Case report: In this retrospective observational trial, it has been evaluated efficacy and tolerance of pomalidomide plus dexamethasone (PD) as salvage regimen in heavily pretreated patients with relapsed and refractory MM (rrMM), whose prognosis is particularly severe.

Methodology: 57 patients (31 M/26 F), with rrMM, median age at diagnosis 69 years (r. 52–86), and median age at start of treatment 76 years (r.56–90) treated with several lines of treatments (median 7, r. 2–11), every refractory to all the drugs previously received (also Bortezomib, Thalidomide and Lenalidomide), received Pomalidomide-Dexamethasone (Pomalidomide 4 mg for 21 days, Dexamethasone 40 mg days 1, 8, 15, 22, pegfilgrastim day +8) every 28 days, until progression. ISS was equally distributed, and cytogenetic at relapse was evaluable in 14 patients. All the patients had previously been treated with schedule containing bortezomib and IMIDs. 63% (36/57) had undergone at least to a single ASCT. All patients were relapsed and refractory to last therapies received before PD.

Results: Pomalidomide was well tolerated, with grade 3–4 transfusion-dependent anemia in 58% (33/57) of patients, 44% (23/57) grade 3–4 neutropenia (pegfilgrastim in primary prophylaxis was given, no hospitalization was required, no septic shocks were observed), 40% (23/57) grade 3–4 thrombocytopenia without hemorrhagic events and transfusion-dependence. No severe extra-hematologic toxicity was observed. According to IMWG, ORR1 (≥PR) was 47.3% (27/57: 5 CR, 11 VGPR, 7 PR, 4 MR), but, considering that we are evaluating a cohort of heavily pretreated patients, with poor prognosis, another parameter should be considered, ORR2 (≥SD), considering stable disease as a successful result in progressive MM. ORR2 was 77.1% (17 SD). These can be considered as impressive result in this subset of patients. Oral treatment gives a really good compliance, in frail and unfit patients, and response, when present, is always really fast (median time to response: 2 months (r.1–6)), median OS from diagnosis was 94 months (range 21–234), median OS from start of pomalidomide was 9 months (range 1–25). Nine patients have surprisingly achieved a notable response (3 VGPR, 4 PR, 2 MR) after failure of novel agents (i.e. Carfilzomib, Daratumumab and Pomalidomide).

Conclusion: Pomalidomide-dexamethasone has shown significant efficacy and a very good compliance, thanks to oral administration, in a particularly severe setting of heavily pretreated patients, relapsed and refractory to all available therapeutic resources, also after failure of novel agents.

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PP 36

Carfilzomib-lenalidomide-dexamethasone in the management of lenalidomide-refractory multiple myeloma

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Objective: Carfilzomib is an epoxyketone proteasome inhibitor of second generation, proved to be effective and safe in relapsed and refractory Multiple Myeloma (rrMM), in combination with dexamethasone or lenalidomide and dexamethasone.

Case report: In this retrospective observational trial, it has been evaluated efficacy and safety of carfilzomib, in combination with lenalidomide-dexamethasone (KRD) as salvage regimen in patients with rrMM, refractory to lenalidomide, where lenalidomide-based regimens have no proven efficacy.

Methodology: 41 patients (23 M/18 F), with rrMM, median age at diagnosis 63.7 years (r. 43–82), median age at start of treatment 67 years (r. 48–84) previously treated with several lines of treatments (median 3, r. 2–11), underwent to KRD regimen (ASPIRE trial schedule) for a median treatment cycles of 8 (r 2–18). ISS was equally distributed, and all patients had previously been treated with bortezomib and IMIDs, and were refractory to this agents. 61% (19/31) of them had undergone at least to a single ASCT.

Results: According to IMWG criteria, after a median follow-up of 9 months (r. 2–18), ORR was 68.2% (28/41: 9 CR, 12 VGPR, 7 PR) with 5 progressive diseases (PD) and 8 patients in stable disease (SD): this can be considered as an impressive result in this subset of rrMM patients, refractory to lenalidomide. In particular, for 11 patients, KRD was, after having achieved at least a PR, a bridge to second/third autologous SCT. Median time to response was 1.3 months (r.1–4), median OS from diagnosis was 62 months (r. 9–170), median OS from start of Carfilzomib was 11 months (r. 2–18). Carfilzomib was well tolerated, with grade 2 anemia in 39%(16/41) of patients, successfully managed by ESAs, without necessity of blood transfusions; 29% (12/41) grade 3–4 neutropenia (pegfilgrastim in primary prophylaxis was given, no ospedalization was required, no septic shocks were observed); 34% (14/41) grade 2, 21% (9/41) grade 3 and 12% (5/41) grade 4 thrombocytopenia,

without hemorrhagic events and transfusion-dependency. Moreover, it was observed pneumonia in 39% (16/41) of patients, treated by common antibiotic drugs and always solved. A cardiac monitoring was performed for all patients: hypertension (grade 2–3) in 34% (14/41) of patients; fatigue in 39% (16/31) of patients.

Conclusion: Carfilzomib-Lenalidomide-Dexamethasone has shown significant efficacy in a particularly severe setting of patients, relapsed and refractory to all available therapeutic resources, also lenalidomide, and it could be considered as a bridge to a second autologous or allogenic SCT.

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PP 37

The relationship of hepcidin, soluble transferrine receptor, growth differentiation factor-15 and anemia in multiple myeloma

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Objective: Multiple myeloma is a malignant disease of clonal plasma cells and anemia takes part in most of the patients. Although it is similar to the anemia of chronic disease with many parameters, the exact mechanism has not been clarified. Hepcidin, Growth differentiation factor-15 (GDF-15), soluble transferrin receptor (sTfR) have been investigated in many forms of anemia, especially in chronic diseases and cancers. However, there are few studies investigating their role in anemia in myeloma. In this project, we aimed to determine the relationship between hepcidin, sTfR and GDF-15 levels in multiple myeloma patients and their clinical features such as anemia parameters and disease stage.

Methodology: This study was approved by Duzce University Faculty of Medicine Non-Invasive Ethics Committee with the decision dated 20.01.2015 and numbered 2015/110 and supported by Düzce University Department of Scientific Research Projects with Project number 2015.04.03.336. Multiple myeloma patients who were diagnosed at our hematology clinic were evaluated for the study. Among these newly diagnosed patients, those who received erythrocyte or whole blood transfusion, iron, B12 or folic acid treatment within the last month were excluded and total 28 patients were enrolled. A control group of 28 people was formed from the volunteers without any disease and fasting blood samples were taken from all participants. After reaching the targeted number of patients and control groups, serum hepcidin, sTfR and GDF-15 levels were obtained from these preserved samples by ELISA method.

Results: Although myeloma patients had significantly lower Hb and Hct levels compared to the control group (median Hb 9.95 vs. 13.40 g/dL and median Hct 30.35% vs. 40.00%, $p < 0.001$), none of the GDF-15, hepcidin and sTfR levels showed a significant difference between the myeloma and control groups. Among multiple myeloma patients, we found that the anemic subgroup had significantly lower hepcidin levels than the non-anemic subgroup ($p = 0.043$) but GDF-15 or sTfR levels were not different ($p > 0.05$). When the correlations were examined, GDF-15, hepcidin and sTfR levels showed correlation with each other, while GDF15 was positively correlated with creatinine and sTfR levels were positively correlated with many parameters such as LDH, CRP, ferritin, albumin, creatinine, Hb and ISS stage. None of the levels of GDF-15, hepcidin and sTfR had a significant effect on survival.

Conclusion: Our findings suggested that mediators of chronic inflammation may play an important role in myeloma anemia but there is not always a clear interaction as in chronic disease anemia, there may be mechanisms that include partial response deficiencies and accommodate variable responses according to the characteristics of the patient groups.

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OTHER DISEASES

PP 38

Serum & salivary ferritin levels in iron deficiency anemia is there is a difference?

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Objective: Iron deficiency anemia (IDA) is one of the most important nutritional deficiencies in Egypt. The assessment of serum ferritin has been the gold standard method in the detection of this disease But, this involves the drawing of venous blood, which is invasive and is sometimes physically and psychologically traumatic to the patients, and sometimes it is difficult to withdraw blood from hidden veins. This study is done to estimate and correlate the serum ferritin levels & saliva of patients with IDA. Thus, assessing the effectiveness of saliva as an alternative non-invasive diagnostic tool. This study is done to estimate, compare and correlate the Ferritin level in serum & saliva of iron deficiency anemia patients, to determine whether saliva can be used as a predictive marker to monitor the iron levels in iron deficiency anemia.

Methodology: 60 patients with iron deficiency anemia and 20 healthy subjects as control were chosen for the study. Quantitative estimation of serum and salivary ferritin was performed by solid-phase ELISA, hemoglobin levels were also estimated to confirm the anemic status of the patient.

Results: Increased salivary ferritin level in patients with iron deficiency anemia and negative significant correlation between the salivary ferritin, salivary/serum ferritin ratio, and serum hemoglobin and a significant negative correlation between serum and salivary ferritin.

Conclusion: Salivary ferritin is a noninvasive method for the detection of IDA with a good predictive impact.

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