Treatment of high-risk smoldering multiple myeloma (HRSMM) with Isatuximab, lenalidomide, oral Cyclophosphamide and Dexamethasone: a survival advantage

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INTRODUCTION

High risk smoldering multiple myeloma was treated traditionally with observation only, however; transformation to multiple myeloma takes place within at least 2 years of diagnosis. Some patients do not take serious medical observations, making the transformation more aggressive at presentation. Several trials were conducted, shedding light on treatment smoldering multiple myeloma patients at higher risk to transform into more serious diseases and most studies investigated the role of anti-CD38 along with immune modulators such as Lenalidomide and Dexamethasone.

AIM

In our study we are trying to show the importance of early treatment of HRSMM patients. Those patients are rarely diagnosed in our country because they are followed by physicians other than haemato-oncologists. Some are seen by nephrologists or orthopedists. In this study, we tried to demonstrate the impact of early treatment on progression free survival in those patients.

METHOD

We have included 12 patients diagnosed with HRSMM with ages ranging between 42 and 70 (62 in median) and a male to female ratio of 3:1. All patients diagnosed had 2 out of the following 3 criteria: serum M-protein more than 2 gr/dl, free light chain ratio more than 20 and/or bone marrow plasma cells more than 20%. Patients were treated on 28-day cycles with ISA 20 mg/kg IV on days 1, 8, 15, and 22 of cycle (C) 1, days 1 and 15 of C2-6, and day 1 of C7-30, together with LEN 10 mg PO in continuous, oral Cyclophosphamide 100mg PO in continuous and Dexamethasone 8mg every week. The primary endpoint was overall response rate (ORR) after the 6th cycle. Secondary endpoints were progression-free survival (PFS), defined as time from enrollment to development of symptomatic multiple myeloma, ORR after completion of 18 and 30 cycles, and overall survival (OS).

CONCLUSIONS

The ORR of our study shows that the combination of anti-CD38, immune-modulators, oral chemotherapy and Dexamethasone is a good tolerable combination in high risk smoldering multiple myeloma patients with a good safety profile. Though the number is modest, however; results are comparable with other trials

RESULTS

The overall response rate ORR was 91.6% after the 24th cycle improved from 66.6% after the 6th cycle to 83% after the 12 cycles. Only one patient progressed after the 17 cycles. Complete responses were documented in 7 patients (58%) while all others responded between partial response and very good partial response. Deep response documented to happen between cycle 15 and 21 (17 in median). With a median follow-up of 2 years the progression free survival was 91.6% (95% CI: 86.2-100). Hematologic side effects with grades between 1-2 were documented effects such as nausea, diarrhea, constipation fatigue and skin rashes ranged between 8-32% in general and they were tolerable.

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