



MELANOMA AND MELANOCYTIC NAEVI

## CLINICAL ACTIVITY OF HIGH-DOSE RECOMBINANT INTERFERON- $\alpha$ 1B IN SIXTY-SEVEN PATIENTS WITH STAGE IV MELANOMA: A RETROSPECTIVE REVIEW

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**Background:** Recombinant interferon- $\alpha$ 1b (IFN- $\alpha$ 1b) that differs from IFN- $\alpha$ 2b in amino-acid sequences is biologically and therapeutically active and may be better tolerated than IFN- $\alpha$ 2b in patients with metastatic malignancies. The clinical activity of high-dose recombinant IFN- $\alpha$ 1b has not been well defined in patients with advanced melanoma.

**Objective:** We sought to assess the effectiveness and adverse events of IFN- $\alpha$ 1b in patients with stage IV melanoma.

**Materials and Methods:** We retrospectively reviewed the demographics, treatment histories, clinical outcomes and tolerability of all the patients with metastatic melanoma who were treated with high-dose recombinant IFN- $\alpha$ 1b in our department between February 2014 and August 2017. The patients received subcutaneous injection of recombinant IFN- $\alpha$ 1b at a dose of 30-100MIU of once every other day unless intolerable toxicities or disease progression occurred.

**Results:** Sixty-seven patients with stage IV melanoma (25 M1a, 14 M1b, and 28 M1c) were enrolled. The median overall survival was 17 months (95% CI, 7.009-26.928). The one-year overall survival rate was 57.8%. The most common adverse events of any grade were fever (89.6% of the patients), fatigue (32.8%), alopecia (23.9%), leukopenia (14.9%) and thrombocytopenia (13.4%). Grade 3 and 4 toxicities included fever (ten patients; 14.9%) and fatigue (two patients; 3.0%). Chronic adverse events including anemia, hepatotoxicity and mood disorder were relatively uncommon.

**Conclusion:** Recombinant IFN- $\alpha$ 1b showed promising antitumor efficacy and tolerable toxicity in patients with metastatic melanoma, which needs to be further validated in a prospective randomized trial.

