

1235P Safety of immunotherapy in elderly patients: A retrospective analysis of a phase I unit

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Background: Cancer immunotherapy has been used in patients over 70 years old with controversial results. Several age-associated changes including the dysregulation of the immune system could be involved. The main goal of our study is to retrospectively investigate the safety of immunotherapy in elderly patients enrolled in early phase studies regardless tumor type.

Methods: We retrospectively reviewed all cases of patients ≥ 70 years old enrolled in early phase trials with different immunotherapeutics between January 2016 and March 2018. Eligible patients have received at least one cycle of single agent or a combination of first and/or second generation immune-modulating drugs. The primary aim of the study was to evaluate the safety of such an approach in the elderly population. Toxicity has been graded using the NCI CTCAE v 4.0. Secondary objective was disease control rate (DCR). Fisher test was used to perform the comparison analysis.

Results: We identified 29 patients, of those 21 were eligible and 8 were screening failures. Patients included in the analysis had an ECOG performance status 0-1. Twelve patients were treated with combo regimens (including a backbone of an anti-PD1 in combination with a new generation immune-checkpoint inhibitor) and 9 with monotherapy. Only 2 patients, one treated with combo and one with monotherapy, experienced a grade 3 immuno-related toxicity leading to treatment discontinuation: an autoimmune thyroiditis in one case and an autoimmune hepatitis, histologically proved, in the other one. The most common adverse event (AE) was G1-G2 fatigue that occurred in 33% of patients. Immuno-related AEs of any grade were observed in 22% of patients treated with monotherapy compared to 33% in the combo group. Three out of 9 patients treated with monotherapy had a partial response or a stable disease with a DCR of 33%, whereas in the combo group the observed DCR was 66%. Differences were not statistically significant between the two groups for neither toxicity nor efficacy (p value 0.65 and 0.19, respectively). No complete response was observed.

Conclusions: Our results suggest that immunotherapy is an effective and well tolerated treatment for older patients with solid tumors.

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