SIOG 2017 - Abstract Submission

Track 4: Modern diagnostics & therapeutic areas

Immunotherapies

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COMPREHENSIVE ANALYSIS OF IMMUNE-RELATED TOXICITIES AMONG OLDER ADULTS TREATED ON NOVEL IMMUNOTHERAPIES ON PHASE I CLINICAL TRIALS

I. M. Subbiah [1,*], T. Fujii [2], A. Lui [2], S. Roy [2], R. Khanji [2], K. R. Hess [2], V. Subbiah [2], A. Naing [2], D. S. Hong [2]

[1]Cancer Medicine, [2]MD ANDERSON CANCER CENTER, Houston, United States

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I submit my abstract to be considered for the following award: SIOG Young Investigator Award

Introduction: Cancer remains a disease that disproportionately affects older adults. Despite accounting for the greatest proportion of those with cancer, older patients (age 65 and above) represent a significantly lower proportion of patients included in clinical trials, particularly early phase trials with novel therapeutics. An oft-cited barrier to enrolling an older adult is the trepidation over a higher incidence of toxicities than the middle age subset.

Objectives: To that end, we investigated the participation and incidence of immune related toxicities among older adults receiving treatment on phase 1 immunotherapy trials.

Methods: We queried a prospectively maintained department database of patients with advanced cancers and identified 422 patients treated on immunotherapy-based phase I trials bw 04/2009-09/2015. We gathered baseline clinical characteristics and immune-related adverse events (irAE) such as endocrinopathies, diarrhea/colitis, pneumonitis, constitutional (eg fatigue, fever, anorexia), myalgia, and dermatitis

Results: Overall, 116 of the 422 patients treated were older adults aged 65 years and above (27%, median 70y), 50 were adolescent/young adults (AYA) aged 15 – 39 years (12%, median 30y), 256 mid age aged 40-64years (61%, median 56y). The primary cancers were GI (n = 108, 26%), thoracic/head/neck (n = 84, 20%), GU (n = 54, 13%), and GYN (n = 47, 11%). Among the three age groups, the median PFS was comparable (2.4m older adults, 2.1m AYA, 2.1m mid age). Overall, older adults had a higher incidence of irAE than mid age or AYA (low grade [G1/2] 49% vs 34% vs 34%, p 0.02; high grade [G3/4] 19% vs 11% vs 12%. p 0.14).

When assessing the irAE rates of older adults to AYA and mid age pts, the odds ratio of high grade irAEs was 1.81 (95% CI 1.01, 3.24; p 0.05) and low grade irAEs was 1.85 (95% CI 1.20, 2.85; p 0.0055). Most common low grade (grades 1 and 2) irAEs among all patients were fatigue (n = 76, 18%), dermatitis (n = 59, 14%), fever (n = 29, 7%) and anorexia (n = 28, 7%) – older adults had a higher incidence of low grade fatigue (25% vs 15%, OR 1.84, 95% CI 1.09, 3.10, p 0.025).

Conclusion: Older adults remained underrepresented on immunotherapy-based phase I trials. Older adults did have a higher likelihood of experiencing an immune-related toxicity than the mid age and AYA pts. These findings warrant additional studies on patient selection and vigilant monitoring of senior adults while receiving novel immunotherapies.

Disclosure of Interest: None Declared

Keywords: clinical trial, clinical trial participation, immune-related toxicity, immunotherapy, toxicity