Correlation, in a real-world setting, between clinical-disease characteristics and compliance with immunotherapy in solid metastatic tumors: First results of an Italian CORE-IMMUNO study

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**Background:** Nivolumab, Pembrolizumab and Ipilimumab monotherapy has shown survival benefits in patients (pts) with melanoma, kidney, lung and head-neck cancer. The aim of this study is to evaluate safety and treatment compliance in terms of delays in the administration or withdrawal of drugs due to toxicity, according to disease and clinical characteristics of pts in clinical practice.

**Methods:** In this retrospective study, data were evaluated on pts in the Reggio Emilia Provincial Oncology Network who were treated for solid metastatic tumors with Nivolumab, Pembrolizumab and Ipilimumab monotherapy in clinical practice. The pts included in the study had received at least 1 dose of therapy by December 2017 and were monitored for adverse events (AE) using Common Terminology Criteria for Adverse Events (v. 4.1).

**Results:** A total of 92 pts were analyzed, of which 42 with lung cancer, 35 with melanoma, 12 with kidney cancer and 3 with head-neck cancer. Sixty-five pts (71%) were treated with Nivolumab, 17% with Pembrolizumab and 12% with Ipilimumab. Overall, 36 pts (39%) experienced an immunorelated adverse event (iAE) of any grade; 33/92 pts (36%) presented a G1-2 iAEs, while only 7% had a G3-4. Out of the 92 pts, the immunotherapy of 17% was delayed due to toxicity, but only 5% of pts discontinued treatment due to iAEs. No statistically significant differences in PFS (9.5 vs. 3.9 months, \( p = 0.12 \)) and OS (21.9 vs. 12.2 months, \( p = 0.13 \)) were found between pts who experienced iAEs and those who did not. Cox regression was performed for PFS and OS using sex, performance status (PS), comorbidities, presence of brain metastases, number of previous lines of therapy, number of metastatic sites and age as covariates. For both, only PS (1-2) significantly correlates with poor PFS and OS with respect to PS 0 (\( p < 0.001 \)).

**Conclusions:** The data supports the use of immune checkpoint-inhibitors in pts treated in clinical practice with different solid tumors. These treatments are suitable for elderly pts with multiple comorbidities, pts with brain metastases and heavily pretreated pts. However, the use of these drugs should be evaluated with caution in pts with poor PS.

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