

891P Correlation between immuno-related adverse events (irAEs) occurrence and clinical outcome in metastatic renal cell carcinoma (mRCC) patients treated with nivolumab: IRAENE trial, an Italian multi-institutional retrospective study

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Background: Immunotherapy (IO) has brought dramatic clinical benefits to patients with mRCC. Most patients tolerate IO, but serious irAE have been reported. Some studies indicate the correlation of irAEs and clinical response in other cancer types such as lung cancer and melanoma. For mRCC, the impact of irAE on clinical outcome is unknown.

Methods: A retrospective review of patients with mRCC treated with nivolumab as standard of care between March 2017-January 2018 from 13 Italian centers of the IGO group (Innovators in Genitourinary Oncology) was performed. Patients enrolled in clinical trial or expanded access program were excluded. IrAEs were assessed based on the treating physician diagnosis.

Results: A total of 111 patients (pts) met criteria. Median age was 67 yr, 83 pts (75%) were male. Histology was clear cell in 102 pts (92%) and non clear cell in 9 pts (8%). IrAE was noted in 48 pts (43%) with steroid required in 21 pts (44%). The time from the beginning of nivolumab treatment to the irAE occurrence ranged 1-81 weeks (mean 10 weeks). Most patients received nivolumab as a second or third line of treatment (61% and 37% respectively). The most common irAEs were cutaneous (21%), endocrinologic (17%), gastrointestinal and pulmonary (both 15%). In patients who developed irAE, 2% of complete response (CR), 22% of partial response (PR), 41% of stable disease (SD) and 35% of progression disease (PD) (according to RECIST criteria) were observed versus 0% CR, 7% PR, 37% SD and 57% PD in patients who did not develop irAE. Development of irAE had a statistically significant impact on response rates ($p = 0.007$). There was also no significant association of steroid use with response rates ($p = 0.643$). Because of the short follow up, survival data were not mature at the time of the analysis.

Conclusions: The development of irAE may be correlated with better response to nivolumab. This data may be limited by sample size and retrospective nature. A long-term follow-up is required to determine the impact of irAE on survival in mRCC patients treated with nivolumab.

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