SAFETY AND EFFICACY OF IMMUNE CHECKPOINT INHIBITION IN PATIENTS WITH CANCER AND PREEXISTING AUTOIMMUNE DISEASES: A NATIONWIDE MULTICENTER RETROSPECTIVE STUDY

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Background: Immune Checkpoint Inhibitors (ICI) have revolutionised the management of several cancers, enhancing the anti-tumoral immune response. However, they are responsible for many Immune Related Adverse Effects (IRAE). The aim of this study was to evaluate the safety and efficacy of ICI in patients with PAD.

Methods: Three national expert networks, focusing respectively on skin cancers, gastroenterological and musculoskeletal diseases, collaborated to perform this retrospective study. The Geriatric and Rheumatology Reference Centre in Pau (France) managed the collection of data from each site.

Results: 112 patients were included: 64 men (57.1%), median age 66.5. Most patients received an anti-CTLA-4 inhibitor (53.5%), followed by an anti PD-1 inhibitor (24.2%). Main cancer types were melanoma (n=36, 32.1%), non-small cell lung cancer (n=25, 22.4%) and urothelial cancer (n=21, 18.5%). Most frequent IRAEs were psoriasis and psoriatic arthritis (27.6%), rheumatoid arthritis (17.8%), inflammatory bowel disease (12.5%), spondyloarthritis (4.5%), lupus (6.3%), polymyalgia rheumatica and/or giant-cell arteritis (6.3%). 24 patients (21.6%) were receiving an immunosuppressive therapy (IS) at ICI initiation (including steroids in 15, sDMARD in 10 and rituximab in 1). 37 patients (33%) had an active disease.

Conclusions: PAD flares were frequent (n=47; 42%) and 30.4% of them were severe (grade ≥CTCAE 3–4). 26 patients (56.5%) received an IS treatment for a flare (22 received steroids and 7 a DMARD). Other IRAEs not related to the PAD occurred in 43 patients (38.4%). 41.5% were severe. 23 patients (56.1%) required an IS (including a DMARD in 4). 36 patients (32.1%) discontinued ICI temporarily or definitively because of a flare or an IRAE. One patient died due to an IRAE.

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RHEUMATIC AND MUSCULOSKELETAL ADVERSE EVENTS ASSOCIATED WITH IMMUNE CHECKPOINT INHIBITORS: DATA MINING OF THE US FOOD AND DRUG ADMINISTRATION ADVERSE EVENT REPORTING SYSTEM

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Background: Immune-modulating monoclonal antibodies directed against immune checkpoints (cytotoxic T lymphocyte-associated antigen 4 (CTLA-4), programmed cell death-1 receptor (PD-1) and its ligand PD-L1), have demonstrated tremendous promise in the treatment of diverse solid tumour types, including melanoma, non-small cell lung cancer, among others and have improved survival rates of these cancer patients. However, these advances have created a new set of challenges in identifying and managing toxicities.

Objectives: To identify emerging trends of rheumatic and musculoskeletal adverse events by immune checkpoint inhibitor (ICI) treatment in the US Food and Drug Administration (FDA) Adverse Events Reporting System (FAERS).

Methods: We used AERSMine, an open-access web based application to mine the FAERS database from the first quarter (Q1) of 2011 to the third quarter (Q3) of 2017, approximately 7.1 million patients. Measures of disproportionality were calculated using well-established pharmacovigilance metrics, Relative Risks (RR) and Drug Administration (FDA) Adverse Event Reporting System (FAERS).

Results: Among all 925,122 reports included in the FAERS. Fisher positive pts.

Conclusions: PAD flares and other IRAEs are frequent during ICI therapy and may be severe. The OS, ORR and PFS seem high in patients with PAD. The occurrence of a flare/IRAE is associated to a better outcome, gain lost when IS are used, while ICI discontinuation has no impact on PFS. Further prospective studies are needed to confirm our findings.

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