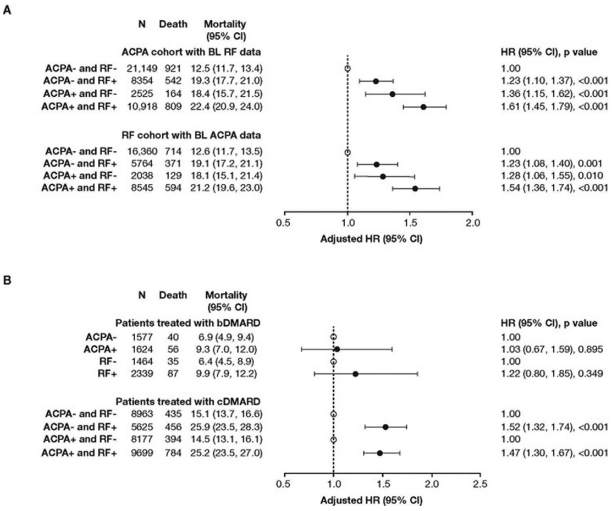

Abstract OP0195 – Figure 1 Mortality rates and HRs in patients categorised by (A) double ACPA and RF serostatus; (B) serostatus and DMARD exposure

Conclusions: Elevated ACPA and RF titres were independently associated with increased mortality among pts with RA. The associations between ACPA/RF and mortality persisted in those treated with cDMARDs but not with bDMARDs. Further studies are warranted to evaluate the effect of bDMARDs on mortality in seropositive pts.

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OP0196 SAFETY AND EFFICACY OF IMMUNE CHECKPOINT INHIBITORS IN PATIENTS WITH CANCER AND PREEXISTING AUTOIMMUNE DISEASES: A NATIONWIDE MULTICENTER RETROSPECTIVE STUDY

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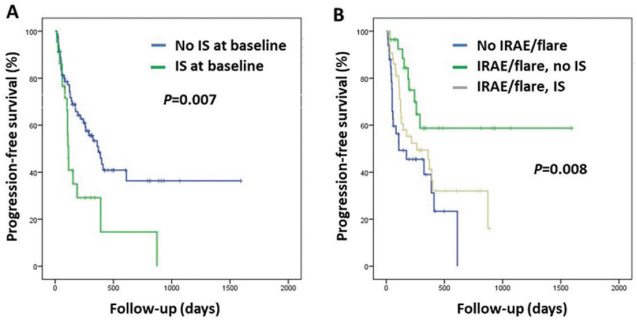
Background: Immune Checkpoint Inhibitors (ICI) have revolutionised the management of several cancers, enhancing the anti-tumoral immune response. However they are responsible for many Immune Related Adverse Effects (IRAE), and therefore most patients with Preexisting Autoimmune Diseases (PAD) have been excluded from clinical trials.
Objectives: 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, thoracic cancers and inflammatory diseases participated in this study. All patients who received an ICI despite a PAD in clinical practice were included in this nationwide retrospective study.
Results: 112 patients were included: 64 men (57.1%), median age 66.5. Most patients received an anti-PD1 or anti-PD-L1 drug (84.8%). Main cancer types were melanoma (n=66, 58.9%) and Non-Small Cell Lung Carcinoma (NSCLC) (n=40; 35.7%). Median follow-up was 8 months [0–52].
Most frequent PAD 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.
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.
Concerning the anti-tumoral response, the Overall Response Rate (ORR) was 48.3% for melanoma and 53.8% for NSCLC. The median Progression Free Survival (PFS) was 12.4 months for melanoma and 9.7 for NSCLC. Median overall survival (OS) was not reached in any group. PFS and OS were shorter in patients receiving an IS treatment at ICI initiation (p=0.007, figure 1A, and p=0.003, respectively). PFS and OS were longer in patients who experienced a PAD flare or other IRAE, but this gain was lost when an IS was used to treat the flare/IRAE (p=0.008, figure 1B, and p=0.01, respectively). Conversely, this gain was not impacted with ICI discontinuation.



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.

Disclosure of Interest: None declared
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OP0197 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 safety signals (information component, (IC)), in a subset of patients with a cancer diagnosis. Terminology used for categorization of adverse events was as included in the FAERS. Fisher's exact test was used to determine significant adverse event differences by ICI treatment and age.
Results: We identified 30 939 unique patients with cancer and reports of immune checkpoint inhibitor associated toxicities. More than half of these reports were in relation with anti PD-1 inhibitors. Statistically significant adverse events associated with ICI therapy identified as toxicity signals with different agents included:
NIVOLUMAB: myositis (n=102; RR, 1.35; p<0.01; IC, 0.43), rheumatoid arthritis (n=67; RR, 1.52; IC, 0.61), psoriatic arthropathy (n=20; RR, 1.93, IC, 0.95),