Methods: A retrospective series of 130 consecutive patients (pts) treated with anti PD-1/PD-L1 or anti CTLA-4 agents from Jan 2012 to Dec 2017 was analyzed. IrAEs were graded according to CTCAE v.4.0. The aim of the study was to evaluate changes in serum markers in pts with irAEs onset. Wilcoxon's signed rank test was used to assess the statistical significance of changes in biomarkers. Gray's test was used to assess differences in the cumulative incidence function of irAEs among groups of pts.

Results: Pts with a diagnosis of NSCLC n = 64 (49%), melanoma n = 55 (42%), kidney n = 9 (7%) and others n = 2 (2%) were investigated. Median age was 69 years. Baseline ECOG PS was ≤ 1 in 96% of the pts. ICI represented first line treatment for 27% pts, second line for 57% and third or further line for the remaining 16%. In detail, 18% were treated with ipilimumab and 82% with anti PD-1/PD-L1 agents (nivolumab 60%, pembrolizumab 21%, atezolizumab 1%). Overall, 41 (36% of pts) irAEs occurred, 39% of those were grade 1, 39% grade 2, 15% grade 3 and 7% grade 4. Among pts who developed irAEs, 50% (21 pts) required immunosuppressive treatment, 25% (11 pts) needed hospitalization and 25% (11 pts) required ICI discontinuation. In patients with irAEs, eosinophilic count increased significantly from the therapy start ($p = 0.03$). Higher NLR (neutrophil to lymphocytes ratio) was associated with lower risk to develop colitis or diarrhea ($p = 0.04$). Additionally, absolute lymphocytic count decreased in patients with irAEs ($p = 0.07$) and monocyte count increased in patients with irAEs ($p = 0.07$) and endocrine irAE ($p = 0.06$). No statistically significant differences in irAEs incidence were seen according to age ($>$ or ≤ 65 years) or sex. Ipilimumab had higher rates of irAEs ($p = 0.03$).

Conclusions: These results suggest changes in the white cell subpopulation count in pts who experience irAEs. Further studies are needed to confirm our findings.

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1198P Serum markers as predictors of immune checkpoint inhibitors (ICI) related adverse events in a real-world scenario

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Background: Immune checkpoint inhibitors (ICI), both anti CTLA-4 and anti PD-1/PD-L1 agents, have drastically changed the cancer therapies landscape. However, by unleashing the host immune system, a new class of immune related adverse events (irAEs) have emerged. It is still unknown if any biomarker may predict irAEs onset.