

162P Monitoring of blood serum amyloid (SAA) to predict outcome of first-line pembrolizumab (P) in patients (pts) with advanced non-small cell lung cancer (ANSCCL)

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Background: In melanoma pts, SAA inhibits the anti-tumor immune response by the expansion of IL-10-secreting neutrophils. We previously found that baseline high SAA was associated with early progressive disease (PD) in small cohort of ANSCCL pts receiving up-front P. Here we explored the relationship between dynamic monitoring of SAA and survival outcomes in an enlarged cohort.

Methods: Pts with ANSCCL (PD-L1 $\geq 50\%$) receiving upfront P at our institution, were prospectively evaluated for blood SAA and radiological response at baseline and every 9 weeks during the treatment. The primary endpoint was progression-free survival (PFS), and secondary endpoints were overall survival (OS) and PD rate. The most accurate SAA cut-off to predict PFS was established with a ROC-analysis.

Results: We enrolled 37 consecutive pts. Pts characteristics: male/female (70/30%), number of sites $<3/\geq 3$ (30/70%), ECOG PS 0/ ≥ 1 (38/62%); never/former or current smokers (54/46%); median age 72.5 (range 59-86) years. Baseline SAA was $>$ the ROC-derived cut-off (73.9 mg/L, AUC 0.77, 95% CI 0.6-0.9, $p=0.002$) in 11 (30%) pts. After a median follow-up of 11.5 months (m), pts with pre-treatment high SAA achieved worse PFS (1.4 vs not reached [NR], HR 0.11, 95%CI 0.03-0.41, $p < 0.0001$) and OS (7.2 vs NR, HR 0.07, 95%CI 0.01-0.37, $p < 0.0001$) compared with those having lower level. Baseline high SAA was also related to PD ($p < 0.05$). Combining SAA at baseline and the dynamic monitoring, the median PFS was 1.4 m (95%CI 0.6-4.4) when SAA remained high ($n = 10$) while was not reached at-12 m when SAA remained low ($n = 12$) or changed ($n = 7$) ($p < 0.0001$). The SAA monitoring was also associated with OS ($p = 0.0003$); the worst prognosis (median 7.2 m, 95%CI 5.4-13.6) was observed in pts maintaining high SAA.

Conclusions: Baseline high SAA predicts poor outcome in ANSCCL pts receiving 1st line P, supporting the potential immunosuppressive role. Considering the strong relationship between SAA monitoring and survival outcomes, the acquired resistance to P could be early and easily detected with a simple blood test. This prospective study is currently ongoing to increase the power and to confirm the predictive role of SAA including a control group.

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