

cutoff of $\geq 50\%$. Among 202 cases with available clinical and expression data, no significant association was observed between PD-L1 expression and clinical outcome. We identified a 12-gene signature from mRNA microarray using the Minimax Concave Penalty (MCP) regression method with an AUC of 0.92 at $\geq 5\%$ TPS cutoff. A subset of 138 miRNAs was shown to be significantly differentially expressed between PD-L1 positive and PD-L1 negative groups at false discovery rate (FDR) of 0.05 with TPS cutoffs of $\geq 1\%$, $\geq 5\%$ and $\geq 10\%$. No miRNAs were found to be significantly differentially expressed between the groups using a TPS cutoff of $\geq 50\%$. Gene Set Enrichment Analysis (GSEA) identified two pathways with gene sets that were significantly enriched (FDR < 0.05) in the PD-L1 negative group. No significant association was found between tumor mutation burden and PD-L1 expression level. **Conclusion:** PD-L1 expression prevalence is lower in early-stage lung SCC than in advanced NSCLC. No significant association was found between PD-L1 expression and prognosis in this cohort. Both mRNA gene signatures and miRNAs were identified to be predictive of PD-L1 expression. Through GSEA, two distinct gene sets were identified with expression correlated to PD-L1, one comprising genes related to ovary and another related to collagens and extracellular matrix (ECM). No significant association was found between tumor mutation burden and PD-L1 expression level. Following validation, these predictive signatures could be used to select patients with positive PD-L1 expression who may benefit from immunotherapy. **Keywords:** PD-L1, gene signatures, early stage lung squamous cell carcinoma

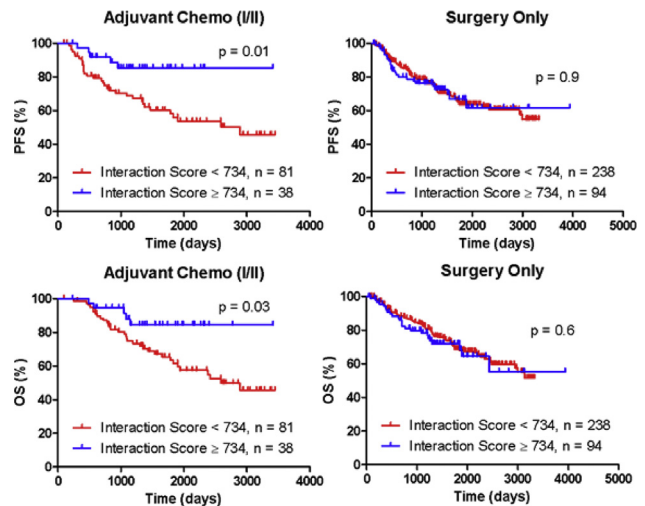
MA 13.03

Quantitative Spatial Profiling of PD-1/PD-L1 Interaction Predicts Response to Adjuvant Chemotherapy Non-Small-Cell Lung Cancer

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Background: Adjuvant chemotherapy (ACT) for ES-NSCLC has a modest improvement in survival but it is often associated with serious adverse effects. Thus, identifying subgroups of ES-NSCLC patients who may benefit from ACT is of high clinical relevance. We evaluated the prognostic and predictive role of quantitative spatial profiling of PD-1/PD-L1 interaction in the tumor cells of ES-NSCLC patients. **Method:** 451 whole tissue sections of formalin-fixed, paraffin embedded surgical resection specimens from ES-NSCLC patients with/without ACT were tested with a multiplexed fluorescence immunohistochemistry assay to detect PD-1, PD-L1, cytokeratin and DAPI labeling. Fluorescence Images were acquired on the Perkin Elmer Vectra platform and analyzed with AQUA® algorithms to determine the percent positivity of each biomarker as well as the co-localization of PD-1 and PD-L1 (the Interaction Score). **Result:** High PD-1/PD-L1 Interaction Scores correlated with improved progression-free and overall survival for ES-NSCLC patients receiving ACT after surgery ($p = 0.01$) whereas no difference in survival was observed for patients who received surgery alone ($p = 0.9$) (Fig 1). Interestingly, the levels of PD-1 or PD-L1 alone did not demonstrate any difference in survival for surgery + ACT or surgery alone patient populations. **Conclusion:** PD-1/PD-L1 Interaction Score is predictive of benefit from ACT in patients with ES-NSCLC. Future studies will determine if this tool can be used to select patients that may be spared chemotherapy without compromising outcome. **Keywords:** Biomarkers, early stage non-small cell lung cancer, adjuvant chemotherapy



MA 13.04

Adjuvant Systemic Therapy in Patients with Early-Stage Non-Small Cell Lung Cancer (NSCLC) Treated with Stereotactic Body Radiation Therapy

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Background: Stereotactic body radiation therapy (SBRT) is currently the standard of care for inoperable patients with early stage non-small cell lung cancer (NSCLC). Despite this, $\approx 20\%$ will relapse at 2 years. While adjuvant chemotherapy is recommended for surgically resected patients with early stage NSCLC (IB-IIIA), data on the role of adjuvant systemic therapy following SBRT for early stage NSCLC are sparse. The goal of this study was to evaluate the role of adjuvant chemotherapy following SBRT in early-stage, inoperable NSCLC. **Method:** Adults diagnosed with early-stage (clinical stage I and II) between the years of 2004 and 2013 were identified from the National Cancer Database (NCDB). Variables abstracted included: age, gender, clinical stage, race, comorbidity, insurance status, treating facility, treatment received and survival. Chi-square tests were used to compare clinical characteristics by therapy type. Kaplan-Meier, Cox regression, and propensity score analyses were employed for survival analyses. **Result:** Data from 12,414 patients with early-stage NSCLC were analyzed. Of these, 75.6% and 25.4% had clinical stage I and II disease, respectively. A total of 9,164 (73.6%) patients received SBRT alone and 3,268 (26.4%) had SBRT followed by chemotherapy. Among patients with clinical stage I, 83.5% received SBRT alone and 16.5% received SBRT followed by chemotherapy. Among those with clinical stage II, 43% received SBRT alone while 57% received SBRT followed by systemic therapy. On multivariate analysis, increasing age, male gender and stage II disease were associated with worse overall survival (OS). There was evidence of a clinical stage by treatment interaction ($p < 0.001$). When treatment effect was analyzed by stage after adjusting for age and gender, patients with stage I treated with SBRT alone had a better median OS, 26.2 months compared to 22.4 months in the combined arm (HR=0.78; $p < 0.001$; CI: 0.73-0.83). In contrast, among patients with stage II NSCLC, median OS was 15 months in the