European Respiratory Society
Annual Congress 2012

Abstract Number: 3550

Publication Number: P3678

Abstract Group: 1.5. Diffuse Parenchymal Lung Disease

Keyword 1: Sarcoidosis **Keyword 2:** Biomarkers **Keyword 3:** Idiopathic pulmonary fibrosis

Title: A combinational approach to optimize biomarkers efficacy in identifying patients with sarcoidosis and monitoring respiratory functional worsening

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Body: Background Sarcoidosis is a multisystemic granulomatous disease of unknown aetiology which affects lungs and lymphatic system.Its diagnosis is established by histologic evidence of non-caseating granuloma and the clinical course is unpredictable. Aims We aimed to investigate whether a panel of biomarkers combined together may help identify sarcoidosis and predict its functional worsening. Methods We analyzed 30 subjects with sarcoidosis and 34 with IPF. Participants underwent PFTs, radiologic investigations, and fiberoptic bronchoscopy. We examined BALF cellular profiles and BALF and serum concentrations of ECP, MPO, tryptase, procollagenIII, sIL-2R, IL-6, and TNFα. Results The linear predictor score,based on the combination of BALF lymphocytes, CD4, CD8,and ECP, correctly allocated 29 patients with sarcoidosis (97% of correct classification; 95% CI, 84.4%-99.8%) and 28 with IPF (82% correct classification; 95% CI, 68.8%-92.2%). The AUC was 0.93. We also analyzed PFTs of participants with sarcoidosis during a 2-years follow-up period. At revaluation 76% of participants had stable disease, and 24% experienced a worsening of the respiratory function. The combination of BALF neutrophil percentage, ECP, and tryptase, yielded a 100% correct classification of patients (95% CI, 90.6%-100%); the AUC was 1. None of the markers analyzed as a single variable reached a similar allocation rate and a dissatisfying discrimination was obtained using markers from peripheral blood. Conclusion This combinational method could be a valuable approach to optimize biomarkers performance in the effort to identify sarcoidosis and to predict its clinical course.