

European Respiratory Society Annual Congress 2013

Abstract Number: 2729

Publication Number: P2783

Abstract Group: 10.2. Tuberculosis

Keyword 1: IGRA (Interferon [gamma]) **Keyword 2:** Tuberculosis - diagnosis **Keyword 3:** No keyword

Title: Utility of a T-cell interferon- γ release assay for the diagnosis of tuberculous serositis: A prospective study in Beijing, China

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Body: Background. The aim of this study was to evaluate the diagnostic efficiency of T-SPOT.TB on serous effusion mononuclear cells (SEMC) for diagnosing tuberculous serositis in a high TB burden area. Methods. The present prospective study enrolled patients with suspected tuberculous serositis in a tertiary referral hospital in Beijing, China, to investigate the diagnostic sensitivity, specificity, predictive value(PV), and likelihood ratio(LR) of these tests. Clinical assessment, T-SPOT.TB on SEMC, and T-SPOT.TB on PBMC were performed. Test results were compared with the final confirmed diagnosis. Results. Of the 187 participants, 74(39.6%) were microbiologically or clinically diagnosed as tuberculous serositis and 93(49.7%) were ruled out. The remaining 20(10.7%) patients were clinically indeterminate. Compared to that on PBMC, T-SPOT.TB on SEMC showed higher sensitivity(91.9%vs73.0%, $P=0.002$), specificity(87.1%vs.73.1%, $P=0.017$), PPV(85.0%vs.68.4%, $P=0.013$), NPV(93.1%vs.77.3%, $P=0.003$), LR+(7.12vs.2.72)and LR-(0.09vs.0.37), respectively. The frequencies of spot forming cells(SFCs) for T-SPOT.TB on SEMC were 636 per million SEMC(IQR,143-3443) in patients with tuberculous serositis, which were 4.6-fold(IQR: 1.3-14.3) higher than those of PBMC. By ROC curve analysis, a cut-off value of 56 SFCs per million SEMC for T-SPOT.TB on SEMC showed a sensitivity of 90.5% and specificity of 89.2% for the diagnosis of tuberculous serositis. Conclusions. T-SPOT.TB on SEMC could be an accurate diagnostic method for tuberculous serositis in TB endemic settings. And 56 SFCs per million SEMC might be the optimal cut-off value to diagnose tuberculous serositis.