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Title: Rapid diagnosis of pulmonary tuberculosis by an enzyme-linked immunospot assay using induced sputum cells

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Body: Background The purpose of this study was to evaluate the diagnostic utility and predictors for determinate results of an enzyme-linked immunospot assay using induced sputum cells (IS ELISPOT) for a rapid diagnosis of pulmonary tuberculosis (TB). Methods Subjects suspected of pulmonary TB who had either sputum acid fast bacilli smear-negative or not producing sputum spontaneously were prospectively enrolled in the study. ELISPOT assay was performed using cells from induced sputum. Results A total of 43 subjects, including 25 with TB (TB group) and 18 with non-TB disease (non-TB group) were enrolled in the study. Results of IS ELISPOT were determinate in only 17/43 (39%) subjects, but all of determinate results were consistent with the final diagnosis. Of the 43 sputum samples, 11 (26%) were inadequate to perform IS ELISPOT. Of 32 adequate sputum samples, the proportion of determinate results was significantly higher in the TB group (75%, 15/20) than in the non-TB group (17%, 2/12) ($p = 0.002$). Smear positivity and extent of chest radiograph were not predictors for determinate results in the TB group. Sensitivity of IS ELISPOT (75%, 9/12) was higher than that of TB-PCR (25%, 3/12) in smear-negative TB. Conclusion IS ELISPOT, in its current format, is not clinically useful because of the high proportion of inconclusive results. However, in the TB group, IS ELISPOT showed relatively high diagnostic value and accuracy regardless of smear positivity. IS ELISPOT may provide additional diagnostic yield for microbiological tools in the rapid diagnosis of smear-negative TB.