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Evaluation of a CFP32-based serological test for the diagnosis of tuberculosis in populations with different levels of exposure

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Introduction: In previous study we have reported the development of a serological test using Pichia pastoris recombinant CFP32 antigen, a virulence factor of Mycobacterium tuberculosis (MTB), with both high sensitivity and specificity in the Tunisian population. In this study, we aimed to assess the ability of the CFP32 serological test, to discriminate between TB patients and non-TB among people of different ethnic origins.

Materials & Methods: Serum samples were obtained from 224 donors from different countries, divided into two groups: i. samples from Tunisian cohort (intermediate endemicity) including TB patients and their contacts ii. Samples from WHO banked sera (obtained from sub-Saharan African and Latin American countries with high endemicity) including TB patients and TB suspected individuals. Receiver operating curve (ROC) was used to evaluate the performance of the CFP32 serological test.

Results: CFP32 specific antibody levels in the TB patients was significantly higher than non-TB controls in Tunisian group ($p<10^{-4}$), Sub-Saharan African group ($p<10^{-3}$) and Latin American group ($p<10^{-4}$). Considering all groups together, the area of the ROC curve was 0.77 (95%CI, 0.70-0.83). The cutoff level was set at 0.63, giving the optimal combination between sensitivity (70%, CI95%: 60-79) and specificity (73%, CI95%: 63-81).

Conclusion: Although CFP32 single antigen serological test did not achieve excellent sensitivity and specificity, a combination of CFP32 with other select antigens and particularly stage-specific infection antigens could be used to improve performance of a serological test regardless of TB incidence and latent infection.

Biography

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