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Title: Correlation of Mycobacterium tuberculosis –specific and non-specific quantitative T cell IFN- γ responses with mycobacillary load in a HIV-prevalent high burden setting

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Body: Background: Measures of bacillary load in patients with tuberculosis (TB) may be useful for predicting and monitoring response to treatment. The relationship between quantitative T-cell responses and mycobacterial load is poorly studied. We hypothesised that, in a high burden setting, the magnitude of mycobacterial antigen-specific and non-specific T-cell IFN- γ responses would correlate with (a) bacterial load and (b) culture conversion in patients undergoing treatment. Methods: We compared the magnitude of purified-protein-derivative (PPD) and RD1-specific (TSPOT.TB and QFT-GIT) peripheral blood IFN- γ T-cell responses with associates of sputum bacillary load [liquid culture time-to-positivity, smear-microscopy grade, Xpert-MTB/RIF Ct values, and the presence of cavities on a chest radiograph] in 513 individuals with suspected TB in Cape Town, South Africa. Serial IGRA responses were evaluated at 2 (n=35) and 6 months (n=13) post-treatment initiation. Results: PPD and RD1-specific IFN- γ responses were not associated with culture TTP (p-values for TSPOT.TB, QFT-GIT and PPD of 0.11, 0.07 and 0.09), smear-grade (0.42, 0.09, and 0.85), Ct values (0.70, 0.91, and 0.49) or the presence of cavities on the chest radiograph (0.12, >0.05, and 0.08). 2-month IGRA conversion rates (positive to negative) were negligible [<10% for TSPOT.TB (3/28) and QFT-GIT (1/29)] and lower compared to culture [60% (21/35); p<0.01]. Conclusions: In a high-burden setting M.tuberculosis-specific and non-specific antigen-driven IFN- γ responses do not correlate with bacillary load and are not useful for prognostication or treatment monitoring.