

O0013 Evaluation of the effect of HIV infection on QuantiFERON-Plus results in patients with active and latent tuberculosis infection

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Background: In 2017, tuberculosis (TB) caused an estimated 300.000 deaths among HIV-positive people (WHO TB-report 2018). Treatment for latent TB infection (LTBI) is strongly recommended in HIV-infected people. The QuantiFERON-TB-Plus (QFT-P) is one of the IGRAs worldwide used to diagnose LTBI. Aim of this study was to evaluate the effect of HIV-infection on QFT-P test in a low TB endemic country.

Materials/methods: We prospectively enrolled 131 subjects with HIV-infection: 26 had active TB (22 microbiologically diagnosed; 4 clinically diagnosed), 39 had a LTBI (QFT-P positive) and 66 had not *M.tuberculosis*-infection.

Results: HIV-TB patients had higher RNA copies/ml (HIV-TB: median 81590; HIV-LTBI: median 69; $p \leq 0.0001$) and lower CD4/mm³ (HIV-TB: median 148, HIV-LTBI: median 610, $p \leq 0.0001$) compared to HIV-LTBI.

Stratifying the IFN γ values according the CD4-count, we observed that active-TB patients with a CD4-count $>200 < 600$ CD4/mm³, had the higher IFN γ values compared to other CD4-groups (not significant). We observed a similar number of positive responses to TB1 and TB2 stimulation in both HIV-TB (TB1: 18/26; TB2: 20/26) and HIV-LTBI patients (TB1: 37/39; TB2: 36/39). Analyzing the IFN γ values (IU/mL), we found similar levels in both HIV-TB and HIV-LTBI (HIV TB: TB1 median 1.6, TB2 median 2; HIV-LTBI: TB1 median 2.3, TB2 median 2.2). The majority of IFN γ values of HIV-TB and HIV-LTBI fell out of the uncertain range of 0.2-0.7 IU/mL (Nemes AJRCCM 2017). Differently, HIV-infected patients without *M.tuberculosis*-infection had IFN γ value below the 0.2 IU/mL.

Comparing QFT-P results with a cohort of LTBI and active-TB patients without HIV-infection (Petruccioli Scientific Report 2018), we observed a significant lower IFN γ level in HIV-LTBI compared to LTBI (TB1: $p=0.04$; TB2: $p=0.05$). Sensitivity of the test in HIV-TB was 70%, whereas in active-TB patients without HIV was 93%.

Conclusions: In conclusion, these results indicate that HIV-infection and consequently the level of CD4-counts have an impact on the IFN γ levels and on the sensitivity of the test. Notably, the few results inside the uncertain zone suggest that the test is not dependent on technical issues. More studies are necessary to understand the effect of HIV-infection on the accuracy of QFT-P in the HIV-infected population.

