Summary

Pulmonary Tuberculosis is a Major Global Health Problem in the 21st Century. The QuantiFERON-TB Gold assay is an ELISA assay that measures the production of IFN-γ by T-cells after sensitization with *M. tuberculosis* antigens using whole blood.

This work aimed to study the degree of sensitivity and specificity of QFT-Gold IT assay.

The study included 40 Patients together with 10 age and sex matched controls previously vaccinated by BCG with positive tuberculin test. Patients were subdivided into two groups:

Group (1): included 20 patients with Sputum positive for TB.

Group (2): included 20 patients that were suspected to catch TB infection, guided by: clinical examination (Symptoms and signs) and radiological investigations with smear negative for TB.

The age in group I was 28.4±4.7, in group II was 27.3±5.1 and in control was 28.9±4.6**.** It was noticed that all groups were age matched and there were no statistical differences between them.

In group I: male patients were 15 (30%) while female patients were 5 (10%), in group II: male patients were 13 (26%) while female patients were 7 (14%) and in control: male patients were 8 (16%) while female patients were 2 (4%)**.** It was noticed that all groups were sex matched and there were no statistical differences between them.

In group I: urban patients were 14 (28%) while rural patients were 6 (12%), in group II: urban patients were 12 (24%) while rural patients were 8 (16%) and in control: urban patients were 7 (14%) while rural patients were 3 (6%)**.** It was noticed that there were no statistical differences between all groups regarding residence.

According to symptoms: 9 patients (45%) of group I had chronic cough, 3 patients (15%) had hemoptysis and 12 patients (60%) had toxemia. As for group II**:** 5 patients (25%) had chronic cough, 1 patient (5%) had hemoptysis and 3 patients (15%) had toxemia. Comparison between group I and group II according to symptoms was statistically insignificant.

According to signs: 13 patients (65%) of group I had crepitations and 5 patients (25%) had signs of toxemia. As for group II**:** 5 patients (25%) had crepitations and 1 patient (5%) had signs of toxemia. Comparison between group I and group II according to signs was statistically insignificant.

Five patients (25%) of group I had X-ray findings, while only 1 patient (5%) of group II had X-ray findings. Comparison between group I and group II according to X-ray findings was statistically insignificant.

Evaluation of Tuberculin test as a diagnostic test in relation to culture showed that: Tuberculin test sensitivity = 94.7%, specificity = 80%, predictive value positive (PVP) = 90% which means that 90%

of the disease positive patients gave positive tuberculin test and predictive value negative (PVN) = 66.7% which means that 66.7% of the disease negative patients gave negative tuberculin test.

Evaluation of QFT- Gold IT test as a diagnostic test for TB in relation to culture showed that: QFT- Gold IT test sensitivity = 100%, specificity = 100%, predictive value positive (PVP) = 100% which means that 100% of the disease positive patients gave positive QFT-Gold IT test and predictive value negative (PVN) = 100% which means that 100% of the disease negative patients gave negative QFT- Gold IT test.

Agreement between Tuberculin test and QFT-Gold IT test was a good agreement, where the 'κ' was 0.65 (CI= 0.39-0.91).

In our results, there was a positive correlation between Quantiferon level and severity of infection in sputum, which was statistically significant, where 'r' was 0.92 and P-value was <0.05.

There was also a positive correlation between Quantiferon level and cavitations in X-ray, which was statistically significant, where 'r' was 0.83 and P-value was <0.05.

QFT-Gold IT, have excellent sensitivity and specificity that is unaffected by BCG vaccination or other variables. TST specificity is high in non-BCG-vaccinated populations but low and variable in BCG-vaccinated populations. There is a good agreement between the clinical findings and the QuantiFERON-TB test results.