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Opinion Article

Diagnosis of Tuberculosis Using QuantiFERON-TB Gold In-Tube (QFT-GIT) Test

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DESCRIPTION

Tuberculosis (TB) continues to be a major global health concern. Despite significant efforts to control the disease, the disease's mortality and incidence rates remain extremely high. The ability to diagnose TB in its early stages is critical for controlling its spread. Smear microscopy is widely available, but it is insensitive. A smear-positive result requires at least 5,000 *bacilli* per mL of sputum. Furthermore, a positive result is not limited to *Mycobacterium tuberculosis*. Mycobacterial culture, on the other hand, usually takes several weeks to produce final results. It also necessitates specialized laboratory equipment, technicians with additional skills, and bio-safety conditions. The sensitive tools that supplement conventional tests are required to guide the initiation of therapy when the diagnosis of tuberculosis disease is uncertain. Interferon-Gamma Release Assays (IGRAs) are immunodiagnostic tools that measure the amount of Interferon-Gamma (IFN-) released by T-cells in response to a *Mycobacterium tuberculosis*-specific antigen. In developed countries, the QFT-GIT test has been widely used to assess the diagnosis of *Mycobacterium tuberculosis* infection. In recent years, studies of QFT-GIT performance in developing countries such as Iran, India, Zambia, Brazil, and others have become more documented. According to current data, the QFT-GIT test is less influenced by prior BCG vaccination and environmental mycobacteria. As a result, the QFT-GIT test is increasingly being used in areas where BCG vaccination coverage is high. Numerous studies have been conducted to evaluate the utility of this test in diagnosing Latent Tuberculosis Infection (LTBI) in various clinical settings. The use of IGRAs in active TB has been controversial, particularly in high prevalence settings. Thailand has a TB epidemic, with an estimated prevalence of 172 per 100,000 people. National guidelines for using IGRA for LTBI screening or TB diagnosis have yet to be established, whereas the TST is the preferred test for detecting TB infection. The QFT-GIT test is currently available and has been used to diagnose LTBI in Thailand. Nonetheless, it has been used in clinical practice for rapid confirmation of TB disease or ruling out active TB in many suspicious cases, particularly when sputum samples are insufficient or non-existent. When compared to other specimens, collecting blood samples may not be as difficult, and QFT-GIT can provide results in as little as two days. Despite its high cost, QFT-GIT may be a valuable additional test for tuberculosis diagnosis. However, data on the utility and efficacy of QFT-GIT for diagnosing active TB in this setting are limited. We investigated the diagnostic potential of the QFT-GIT assay for detecting tuberculosis infection in active TB patients in Thailand, using healthy adults as controls.

QuantiFERON-TB Gold In-Tube (QFT-GIT) for TB diagnosis

The differences in the percentages of QFT-GIT results for the IFN- test in each patient group compared to the controls were statistically significant (p-values 0.05). Due to a low immune response to mitogen antigen in a positive control tube, two cases of active PTB patients had an undetermined or un-interpretable result. 18 (16.07%) of the 112 healthy subjects had an IFN- level greater than 0.35 IU/mL, indicating probable *Mycobacterium tuberculosis* infection or LTBI. One healthy adult had an IFN- level greater than 0.35 IU/mL but less than a quarter of the nil value. This result was interpreted as QFT-GIT negative. Only one subject (0.89%) among the healthy controls had an undetermined result due to a low immune response. The sensitivity and predictive values for the diagnosis of active TB were calculated 48 of the remaining 57 culture-positive patients tested positive for QFT-GIT.

CONCLUSION

There is widespread concern about the utility of QFT-GIT for active TB diagnosis in TB-endemic countries. We conclude that QFT-GIT is useful as a complementary test for diagnosing active TB cases based on our findings. It appeared to be useful for detecting latent tuberculosis in Thailand, a high prevalence setting. IFN- levels were unable to distinguish between active and latent tuberculosis infection. As a result, QFT-GIT cannot be used alone to identify active or latent TB without taking clinical and radiological data into account.

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