Title: Interferon-gamma release assays for pulmonary tuberculosis in low- and middle-income countries

This systematic review presents evidence from a collection of studies evaluating tests or strategies for the diagnosis of tuberculosis (TB). Terms in italics are defined in the TB Evidence Glossary.

Why this review is important: Interferon-gamma release assays (IGRAs) are blood tests that were recently developed as alternatives to the 100 year-old tuberculin skin test (TST) to aid in the diagnosis of latent TB infection (LTBI). IGRAs are mainly used to diagnose LTBI in high-income countries, but are increasingly being used to diagnose active TB in low-income and middle-income countries. Two IGRAs are in current use: QuantiFERON®-TB Gold In-Tube (QFT-GIT), Cellestis Limited, Victoria, Australia and T-SPOT®.TB (TSPOT), Oxford Immunotec, Abingdon, UK.

Objective: To determine the sensitivity and specificity of IGRAs for the diagnosis of pulmonary TB in adults in low- and middle-income countries. To combine results from individual studies in a meta-analysis to obtain summary (pooled) estimates for sensitivity and specificity.

Main findings: 27 studies (TSPOT 10 studies; QFT-GIT 17 studies) involving 590 HIV-uninfected and 844 HIV-infected individuals were included in the review. Among people with HIV-infection, pooled sensitivity estimates were modest: TSPOT 76% (95% CI 45,92; 4 studies); QFT-GIT 60% (95% CI 34,82; 5 studies). Among people without HIV-infection, pooled sensitivity estimates were higher: TSPOT 88% (95% CI 81,95; 4 studies); QFT-GIT 84% (95% CI 78,91; 9 studies). The specificity of both IGRAs was low (<65%), regardless of HIV status.

Authors’ conclusions: As is the case for TST, there is no role for using IGRAs for the diagnosis of pulmonary TB in adults in low-income and middle-income countries, especially in high HIV settings.

Policy implications: In September 2010, the Strategic and Technical Advisory Group (STAG-TB) acknowledged the large body of work and compelling evidence demonstrating the poor performance of current commercial IGRAs in low- and middle-income countries (typically high-TB and/or high HIV settings) and the adverse impact of mis-diagnosis and wasted resources on patients and health services when these tests are used for diagnosis of active TB.


Publications and other resources of related interest

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