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Letter

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Comments on the sensitivity and specificity of a new molecular test for *Mycobacterium tuberculosis* and resistence to rifampin

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Abstract

Recently, Boehme and colleagues described a new automated polymerase-chain-reaction-based test for diagnosing *Mycobacterium tuberculosis* and detecting resistence to rifampin. There are certain issues regarding the sensitivity and specificity calculations in this study, as outlined in the present article.

Dear Editor,

Tuberculosis has become a major concern for rheumatologists, especially with the wide-spread use of tumor necrosis factor (TNF)-alpha antagonists. Boehme and colleagues reported on the use of a new automated polymerase-chain-reaction (PCR)-based test in the September 9, 2010 issue of the New England Journal of Medicine.[1] The authors suggested that the test, termed MTB/RIF test, was fast, easy and reliable in diagnosing tuberculosis and also in detecting resistence to rifampin.

One of the main suggestions of the manuscript is that the MTB/RIF test is very sensitive and specific for the diagnosis of tuberculosis. The specificity of a certain method in the diagnosis of a disease relies a lot on the control groups used. The main issue regarding the specificity of any test in the diagnosis of *Mycobacterium tuberculosis* is its ability to differentiate *Mycobacterium tuberculosis* from non-tuberculous mycobacteria, both of which are acid fast bacilli that can be stained with the Ehrlich-Ziehl-Neelson (EZN) technique. The authors excluded patients who had growth of non-tuberculous mycobacteria from the analysis, which makes it impossible to evaluate the real specificity of the MTB/RIF test.

The sensitivity analysis is also problematic. Patients who were smear and culture negative, but were treated for tuberculosis because of clinical and radiological findings were called the "clinical tuberculosis" group by the authors. However these patients were excluded from the tuberculosis group when sensitivity was calculated. Especially those patients who are clinically diagnosed with tuberculosis and respond well to anti-tuberculosis treatment, but are smear and culture-negative, are an important group to study the performance of the proposed test. A diagnostic test would prove to be valuable if it was shown that it diagnoses such cases better than the routine methods. Otherwise acid smear microscopy is cheaper and widely available, and the percentage of tuberculosis patients that are smear-negative and MTB/RIF-positive, even after performing the latter three times, is not impressively high (20.7%).

Reference

1. Boehme CC, Nabeta P, Hillemann D, et al. Rapid molecular detection of tuberculosis and rifampin resistance. N Engl J Med 2010;363:1005-15.

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