Letters to the Editor

Rapid Immunochromatographic Assay for Diagnosis of Tuberculosis

The development of simple, rapid, and inexpensive diagnostic tools for tuberculosis (TB) is an important goal, particularly in view of the global increase in cases of active TB primarily affecting the developing world (2, 4). Recently, an immunochromatographic assay (AMRAD/ICT Diagnostics, Sydney, Australia) which facilitates the diagnosis of TB by detecting serum antibodies directed against a specific 38-kDa antigen of Mycobacterium tuberculosis has been described (1, 5). Briefly, the test consists of a cardboard folding device containing a nitrocellulose strip and absorbent pads. Antigen secreted by M. tuberculosis during an active infection is immobilized on a line across the strip. When serum or plasma is applied, it flows past the antigen line. If specific antibody to the antigen is present, it binds to the line. Bound antibody is detected by a goat anti-human immunoglobulin G antibody conjugated to colloidal gold particles which give a pink line when bound to human antibody. The whole procedure is completed within 15 min and does not require any additional equipment. The test appears to be highly specific in diagnosing active TB. Prior BCG vaccination, latent infection with M. tuberculosis, or atypical mycobacteria do not appear to give false-positive test results. To our knowledge, published data on experience with this test has been limited to China until now (1, 5). We assessed the AMRAD/ICT test in a university hospital in Germany. To determine its sensitivity and specificity, we compared this rapid membrane-based antibody assay with diagnostic standard procedures.

Results obtained from inpatients with a diagnosis of suspected pulmonary or extrapulmonary TB and from human immunodeficiency virus (HIV)-infected patients with progressed immunodeficiency (CD4+ cell count < 100 µl) who underwent screening investigations were compared with those from routine TB examinations. These included demonstration of acid-fast bacilli in Ziehl-Neelsen-stained smears from bronchoalveolar lavage (BAL) fluid, aspirates, or solid tissues and culture according to standard techniques (3). For all specimens except blood, Löwenstein-Jensen and Stonebrink solid media were used for culture according to standard procedures (3). In addition, a radiometric culture system (BACTEC; Becton Dickinson, Sparks, Md.) was used with Middlebrook 7H13 liquid medium for blood and Middlebrook 7H12 for all other liquid specimens. With the AMRAD/ICT test, we examined 113 serum specimens in total. Of 12 patients with confirmed TB, 8 had pulmonary and 4 had extrapulmonary disease. Four of 8 patients with pulmonary disease and 2 of 4 with extrapulmonary disease had antibodies detected by the test. All 101 culture-negative patients correctly tested negative, including all 7 patients (2 immunocompetent and 5 immunocompromised) from whose blood or BAL fluid atypical mycobacteria were isolated.

For pulmonary TB, overall sensitivities of the test between 70 and 92% and specificities between 92 and 93% have been reported (1, 5). For extrapulmonary TB, the overall sensitivity was 76% and the specificity was 92% (5). Results from our study obtained in a European setting confirm the test’s high specificity (100%) but demonstrate a low sensitivity (50%). Although there is evidence that test results are not impaired by concurrent HIV infection, the sensitivity of the test appears to vary considerably, a finding which may limit its clinical importance. We understand that this rapid test appears not to be useful as a sole diagnostic tool for active TB in comparison with the current diagnostic standards. However, the test may be a valuable adjunct to standard techniques of TB diagnosis. Taking the high specificity into account, the assay might prove to be a suitable instrument for first-line testing for suspected cases in resource-poor countries where access to diagnostic tools is limited and cost efficiency has a high priority.

REFERENCES


Martin P. Grobusch
Dirk Schürmann
Sabine Schwenke
Dieter Teichmann
Eckhard Klein
Medical Clinic (Infectious Diseases)
Charité/Campus Virchow Hospital
Humboldt-University
13353 Berlin, Germany