

Abstract

OBJECTIVE:

To evaluate the use of serodiagnosis for tuberculosis and leprosy using mycobacterial antigen 38 kDa, with kits from Omega laboratories, to detect IgG by enzyme immunoassay (EIA).

METHODS:

The study population consisted of 58 patients with evidence of tuberculous infection (culture of *Mycobacterium tuberculosis* complex or microscopic evidence), of whom 23 had pulmonary and 35 had extrapulmonary disease. There were six subjects who had recently been treated for tuberculosis, 11 patients on treatment for leprosy and 137 patients suspected of having tuberculosis on clinical or radiologic grounds (without laboratory evidence). A control group comprised 35 healthy individuals or patients suffering from diseases other than tuberculosis.

RESULTS:

The tests showed that there was a significant difference in antibody levels between the patients with active pulmonary disease, extrapulmonary tuberculosis and leprosy in comparison with the control group ($p < 0.001$). The sensitivities of the two tests together for proven pulmonary tuberculosis were 100% and 95.7% at 1.0--1.5 and >1.6 EIA cut-off points respectively, while the specificities were 88.5% and 100% at the same cut-off points. The sensitivities for extrapulmonary tuberculosis were 71.4% and only 51.4% at 1.0--1.5 and >1.6 EIA cut-off points. The test was positive in 30 (21.9%) of the 137 suspected patients, while 43 (31.4%) had an equivocal result and the remaining 64 (47.7%) suspects were definitely negative. There was again a significant difference in positivity rates between suspects and the control group.

CONCLUSIONS:

Omega IgG test is useful in the serodiagnosis of active pulmonary tuberculosis and leprosy, but less sensitive in extrapulmonary disease, particularly in children. Equivocal results may only add to the evidence of tuberculosis in early or minimal disease.