Thesis Title Assessment of Immunological Tests for Diagnosis of Mycobacterium tuberculosis Infection

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ABSTRACT

Tuberculosis is still being a global health problem. The definitive diagnosis of this disease depends upon the results of acid-fast staining and culture for *M. tuberculosis*. The low and variable sensitivity of acid-fast staining and the time consuming of culture method are still being the problems encountered. In this study, ELISA technique has been chosen as the mean for the diagnosis of tuberculosis. Two systems of double antibody sandwich ELISA for the detection of mycobacterial antigen were used. Commercial rabbit anti-BCG and rabbit anti-BCG-horseradish peroxidase conjugate were employed in "anti-BCG system" whereas anti-culture filtrate of *M. tuberculosis* (anti-CF) and anti-CF-alkaline phosphatase conjugate were employed in the "anti-CF system". For the assay of sputum specimens, the sensitivity and specificity of the anti-BCG system were 83.54% (66/79) and 93.21% (151/162) respectively. Mycobacterial antigens were also detected in pleural fluid (PF) specimens but not in cerebrospinal fluid (CSF), serum and urine specimens. The

sensitivity and specificity of the anti-CF system were 29.58% (21/71) and 100% (151/151) respectively when sputum specimens were tested. With this anti-CF system, mycobacterial antigens were not detected in any other tested specimens.

Antibodies specific to purified protein derivative (PPD) and plasma membrane (PM) antigen of *M. tuberculosis* were also determined by indirect ELISA. Determination of antibody against PPD antigen in CSF specimens gave the sensitivity and specificity of 52.38% (11/21) and 95% (19/20) whereas those of anti-PM antibody determination were 56.25% (9/16) and 94.74% (18/19) respectively. With sera, anti-PPD antibody determination gave the sensitivity and specificity of 61.54% (24/39) and 78.47% (113/144) while those of anti-PM antibody determination were 60.71% (34/56) and 75.80% (119/157) respectively. With pleural fluid specimens, the sensitivity and specificity were found to be 61.54% (16/26) and 82.35% (14/17) for anti-PPD antibody determination while they were 57.14% (32/56) and 61.36% (27/44) for anti-PM antibody determination respectively.

The results indicated that the detection of mycobacterial antigen in sputum by anti-BCG system of ELISA could be used efficiently for the diagnosis of pulmonary tuberculosis. The determinations of antibodies specific to mycobacterial antigens, both anti-PPD and anti-PM antibodies, in CSF specimens were found to be quite specific for tuberculous meningitis, though the sensitivity of the tests were not high. However, the determinations of specific antibodies in serum and PF specimens have less value for the diagnosis of tuberculosis due to rather low levels of both sensitivity and specificity of the tests.