Efficacy of TB Direct Detection Test from Sputum and Tracheal Aspirates for Diagnosis of Pulmonary Tuberculosis

Aunyakant Jaroensukrungruan¹ Prapaporn Pornsuriyasak²

¹Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok 10400, Thailand, ²Division of Pulmonary and Critical Care Medicine, Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok 10400, Thailand

Background: Thailand is one of the endemic areas of pulmonary tuberculosis (PTB) in South East Asia. Rapid diagnosis and treatment are crucial for prevention of spreading of M. tuberculosis (MTB). Nowadays, standard diagnostic laboratory tests of PTB are based on positive staining and culture of acid-fast bacilli (AFB) in the respiratory samples. Direct detection of MTB with real-time PCR based technique (Anyplex TM) has been developed as a new rapid diagnostic method for TB but the performance of this test from the sputum and tracheal aspirates samples has never been explored.

Objective: To evaluate the efficacy of TB direct detection test (Anyplex TM) from the sputum and tracheal aspirate samples for diagnosis of PTB and to identify factors that might contribute to the performance of TB direct detection test (Anyplex TM).

Methods: A retrospective cohort study of patients suspected of PTB in Ramathibodi Hospital during January 2014 - June 2016 was reviewed. Patients with symptoms of chronic cough, weight loss, or fever, and abnormal chest radiograph were included. Those who had a result of TB direct detection test by Anyplex TM from the sputum or tracheal aspirates were reviewed for diagnosis of PTB: 1) positive AFB staining and culture, or 2) clinical and radiographic improvement at 2 months or 6 months after anti-TB treatment. HIV serology, underlying diseases, pattern and extent of abnormal chest radiograph were reviewed.

Results: A total of 123 patients were enrolled, with 93 (75.6%) PTB, 26 (21.1%) other diagnosis, and 4 (3.3%) undiagnosed. Sensitivity and specificity of TB direct detection test by Anyplex TM was 77.4% and 84.6% with the AUC of 0.75 (95% CI 0.64-0.86). NPV, PPV, and accuracy of Anyplex TM were 22%, 72% and 79%, respectively. Factors that contributed significantly to the performance of the test were cavity pattern (OR 11.8, 95% CI 2.671-52.837), and numbers of lobe involvement on chest radiography (OR 1.2, 95% CI 1.007-1.491).

Conclusion: For diagnosis of PTB, Anyplex TM yields 77.4% sensitivity and 84.6% specificity. Numbers of lobe involvement and cavity pattern on chest radiography increase the performance of the test.

Keywords: TB direct detection test, Efficacy, Sputum aspirate, Tracheal aspirate