Validity of Mycobacterium tuberculosis Antigen Cocktail: ESAT-6, CFP-10, and MPT64 in Sputum and Cerebrospinal Fluid for Pulmonary Tuberculosis and Tuberculous Meningitis Diagnosis

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Abstract

Objective: To determine the validity of tuberculosis (TB) antigen cocktail (ESAT-6, CFP-10 and MPT64) for pulmonary tuberculosis and TB meningitis diagnosis.

Methods: This is a descriptive observational study design. The study was conducted at the Clinical Pathology Laboratory of Dr. Hasan Sadikin General Hospital during September 2012 until March 2013 for the pulmonary tuberculosis study and from January 2014 to May 2014 for the TB meningitis study. The TB antigen cocktail rapid immunochromatography (ICT) test was conducted on all samples. The sputum and cerebrospinal fluid (CSF) were cultured as gold standards.

Results: There were 149 pulmonary and 41 TB meningitis subjects. The sensitivity of rapid ICT TB antigen cocktail for diagnosing pulmonary tuberculosis was 95.7% with a specificity of 87.2%. Of 41 TB meningitis subjects, based on Marais criteria, there were 6 (16%) subjects with a definite TB meningitis, 26 (63%) subjects with probable TB meningitis, and 9 (21%) subjects with possible TB meningitis. The sensitivity and specificity of TB antigen cocktail rapid ICT for TB meningitis diagnosis were 83.3% and 68.5%, respectively.

Conclusions: In this study, rapid ICT TB antigen cocktail (ESAT-6, CFP-10 and MPT64) from sputum sample has good validity for diagnosing a pulmonary tuberculosis. Cerebrospinal fluid sample has moderate validity to diagnose TB meningitis.

Keywords: M. tuberculosis culture, pulmonary TB, TB meningitis, TB antigen cocktail (ESAT-6, CFP-10 and MPT64) rapid ICT

Introduction

Tuberculosis (TB) remains a major public health problem in most developing countries. One-third of the world population carries an asymptomatic infection with Mycobacterium tuberculosis, resulting in eight million new cases of TB and two million deaths every year. Until now, the diagnosis of active tuberculosis is based on microscopy identification for acid-fast bacillus (AFB) and culture of M. tuberculosis. However, microscopy technique is insensitive and conventional culture, although it is more sensitive, is time consuming and requires safety precautions while during the long and tedious culture process an infected individual continues to spread the disease to many other susceptible individuals. The polymerase chain reaction (PCR) method reduces the time detection for culture and identification but requires trained persons, sophisticated equipment, and sophisticated techniques. Rapid and accurate TB diagnostics play an important role in detecting the disease. Currently, antigen secreted by M. tuberculosis (ESAT-6, CFP-10 and MPT64) encoded by the genes of “Region of Difference” (RD)1, RD2 and RD3 gives an opportunity for rapid TB diagnostic.