The Comparative Study of four Diagnostic Tests in Early Diagnosis of Leptospirosis: Results From Thai Lepto-AKI Study

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Background: Leptospirosis is a common zoonotic disease with high morbidity and mortality. One of the key steps in improving leptospirosis outcome is an early diagnosis. With the limitation of unspecific clinical manifestation from other tropical infectious diseases, confirmatory test is still an essential. Currently, the most suitable test for early diagnosis leptospirosis is still in debate.

Objective: This study aimed to evaluate the accuracy of four diagnostic tests including microscopic agglutination test (MAT), direct culture, immunochromatographic rapid test, and real time polymerase chain reaction (RT-PCR), in early diagnosis leptospirosis.

Methods: We conducted a prospective, multicenter, observational study of leptospirosis suspected patients. All patients were enrolled in 15 district hospitals in Sisaket province, Thailand, during February 2016 - July 2017. Blood was serially collected on the first day of enrollment and on day 7. We tested MAT (single titer ≥1:400 or four-fold rising), which was cultured by using EMJH media, immunochromatographic rapid test (IgM, and total Ig), and RT-PCR to detect LipL32 gene.

Results: Two-hundred and sixty-six leptospirosis suspected cases were enrolled. One hundred and eighty one patients had positive in either one of MAT (N=40), culture (N=7), and RT-PCR (N=179). The percentage of PCR positive declined after the first week of fever, while the percentage of rapid test increased after the first week. With the highest percentage of test positive, we used RT-PCR as the reference test to compare the diagnostic accuracy with others. The culture technique had sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of 4.8%, 100%, 100%, and 28.4%, respectively. MAT paired serum test had sensitivity, specificity, PPV, NPV of 32.4%, 93.9%, 94.3%, 31.0%, respectively. While, rapid tests paired serum test had sensitivity, specificity, PPV, and NPV of 74.5%, 50%, 77.6%, and 42.9%, respectively.

Conclusion: Our study demonstrated that RT-PCR test is a more suitable reference test compared to bacteriological and serological techniques for early diagnosis of leptospirosis. While, we are still lacking the antigen specific test and the implementation of RT-PCR test to the endemic area is essential.

Keywords: Leptospirosis, Early diagnosis, Real time PCR, Microscopic agglutination test, Culture, Rapid test