Akurasi pemeriksaan tes cepat leptospira dan polymerase chain reaction leptospira pada pasien suspek leptospirosis = Accuracy of the leptospira rapid test and leptospira polymerase chain reaction diagnostic methods on suspected leptospirosis patient

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Abstrak

Latar Belakang. Leptospirosis merupakan penyakit infeksi di daerah tropis yang terabaikan (neglected infectious diseases) akibat vektor hewan dan kondisi lingkungan. Prevalensi di negara beriklim tropis, khususnya Indonesia cukup tinggi namun tidak terdiagnosis dengan baik. Diagnostik pasti sulit didapat karena uji baku emas leptospirosis, MAT (microscopic agglutination test), di Indonesia masih terbatas aksesnya dan uji alternatif belum banyak diteliti efektifitasnya.
Metode. Penelitian ini menguji kinerja dua jenis alat diagnostik terbaru yaitu tes cepat berbasis IgM (Leptodipstick), dan PCR (polymerase chain reaction) terhadap gen lipl32 dan secY Leptospira dibandingkan uji baku emas MAT pada populasi Indonesia. Subjek penelitian adalah pasien dewasa rawat inap di RSCM pada tahun 2016-2018 yang memenuhi kriteria klinis leptospirosis WHO dan diujikan dengan MAT, tes cepat Leptospira, dan PCR Leptospira. Penelitian ini bersifat potong lintang, dengan variable yang diteliti meliputi data demografi, manifestasi klinis, paparan pekerjaan, paparan vektor ataupun lingkungan, serta hasil pemeriksaan MAT, tes cepat, dan PCR terhadap Leptospira.
Hasil: Terdapat total 30 subjek yang ikut dalam penelitian dengan 11 (36,7%) meninggal dunia. Berdasarkan uji baku emas MAT, 14 (46,67%) dinyatakan reaktif terhadap antibodi Leptospira. Tes cepat Leptospira mendapat nilai sensitivitas 85,71% (95%IK: 57,19-98,22%), serta spesifisitas 62,50% (95%IK: 35,43%-84,80%), dan area di bawah kurva ROC 0,741 (95%IK: 0,549-0,883). Pemeriksaan PCR terhadap gen lipl32, sensitivitas 85,71% (95%IK: 57,19-98,22%), spesifisitas 18,75% (95%IK: 4,05-45,65%), dan area di bawah kurva ROC 0,522 (95%IK: 0,333 – 0,707). Pemeriksaan PCR gen secY, sensitivitas 71,43% (95%IK: 41,90-91,61%), spesifisitas 12,50% (95%IK: 1,55-38,35%), dan area di bawah kurva ROC 0,580 (95%IK: 0,371-0,789). Secara umum, semua uji memiliki sensitivitas yang memuaskan, namun spesifisitas yang buruk dibandingkan dengan MAT. Spesifisitas yang rendah dapat dikaitkan dengan onset penyakit yang sebagian besar berada pada fase akut sehingga belum dapat terdeteksi dengan alat uji yang berbasis antibodi.
Kesimpulan. Spesifisitas tes cepat Leptospira dengan IgM maupun PCR terhadap gen lipl32 dan secY Leptospira sebagai alat penapisan cukup baik. Perlu dilakukan penelitian kinerja diagnostik lanjutan berdasarkan onset penyakit.
.....Background. Leptospirosis is a neglected infectious disease transmitted by animal vectors and environment. The prevalency in tropical Asia-Pacific country, including Indonesia was high. The gold standard test for leptospirosis was microscopic agglutination test (MAT), very limited distribution in Indonesia.
Methods. This study compares the diagnostic profiles of two new diagnostic tools, an IgM-based rapid test (Leptodipstick) and polymerase chain reaction (PCR) of the genes lipl32 and secY of the Leptospira genome, to MAT as the gold standard, in the Indonesian population. Adult inpatients of RSCM in the years 2016-2018 with conformity to the WHO clinical criteria for leptospirosis and undergo MAT test, Leptospira

rapid test, and Leptospira PCR were enrolled in the study. The study was cross-sectional with the examined variable were demographic data, clinical manifestation, occupational exposure, exposure towards animal vectors or environmental conditions, and results of the MAT, Leptospira rapid test, and Leptospira PCR. Results. The study enrolled 30 participants, with 11 (36,7%) deceased in the study period. Based on MAT, 14 participants (46,67%) were considered reactive for Leptospira antibodies. The Leptospira rapid test has a sensitivity of 85.71% (95%CI: 57.19-98.22%), and specificity of 62.50% (95%CI: 35.43%-84.80%), and the area under the ROC curve of 0.741 (95%CI: 0.549-0.883). PCR for the gene lipl32 showed a sensitivity of 85.71% (95%CI: 57.19-98.22%), specificity of 18.75% (95%CI: 4.05-45.65%), and area under the ROC curve of 0.522 (95%CI: 0.333-0.707). PCR for the gene secY showed a sensitivity of 71.43% (95%CI: 41.90-91.61%), specificity of 12.50% (95%CI: 1.55-38.35%), and area under the ROC curve of 0.580 (95%CI: 0.371-0.789). Generally, all tests showed a satisfactory sensitivity, yet very low specificity compared to MAT. Area under the curve showed a low (PCR) to moderate (rapid test) diagnostic value for each test. Low specificity may be tied to the onset of the disease of the study sample that most of them are on acute phase which cannot detected by the alternative test with antibody basis.
Conclusion. The diagnostic parameters of the Leptospira IgM rapid test, and Leptospira PCR with the genes lipl32 and secY are still satisfactory to be used as early diagnostic tools in cases of leptospirosis.