Abstract

Introduction. Human visceral leishmaniasis is a serious public health problem in endemic countries because of its high potential lethality, particularly in children. Rapid diagnosis is essential to early treatment and control of visceral leishmaniasis. Objective. The aim was to compare three serodiagnostic tools for human visceral leishmaniasis. Materials and methods. Three methods were compared: the rK39 dipstick (Kalazar detection test, Inbios International Inc.), ELISA rK26 and direct agglutination test (DAT) (KIT Biomedical Research). Fifty serum samples from patients positive for rK39 ELISA were compared from four endemic provinces in Venezuela: Nueva Esparta (Margarita island), Lara, Anzoátegui and Trujillo. Additional serum samples from 17 healthy volunteers and 25 patients with other diseases were included. The rK39 ELISA served as the baseline standard method. Sensitivity, specificity, positive predictive value, negative predictive value and likelihood ratio were calculated for each test. Results. All methods had a positive correlation with rK39 ELISA (p<0.0001). They showed high sensitivity and specificity. The direct agglutination test and the rK39 dipstick showed high sensitivity values, 89.7% (95% CI: 81.3-98.2%) and 94.2% (95% CI: 87.7-100%), respectively, and high specificity, 81.0% (95% CI: 80.0-99.5%) and 100%. The rK26 ELISA showed good specificity, 99% (95% CI: 95.2-100%), but a very low sensitivity, 37% (95% CI: 23.4-50.2%). Conclusion. Overall results indicated that DAT and rK39 dipstick have the highest specificity and sensitivity. Both are simple, cost-effective and field applicable tests. Therefore, they are recommended for early and accurate diagnosis of visceral leishmaniasis.

Keywords

Leishmaniasis, visceral/diagnosis, agglutination tests, enzyme-linked immunosorbent assay, chromatography, paper, Leishmania infantum, humans, Venezuela.