AN IMMUNOCHEMISTRY TECHNIQUE BASED ANTI-*LEISHMANIA*-ACTIVATED C-KINASE MONOCLONAL ANTIBODY FOR CUTANEOUS LEISHMANIASIS DIAGNOSIS

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We developed an immunohistochemistry technique using an anti-*Leishmania*-activated C-kinase monoclonal antibody for the diagnosis of cutaneous leishmaniasis-CL (IHQ anti-LACK). For that, *Leishmania* (*Viannia*) *braziliensis* LACK sequence (A4HGX7_LEIBR) was submitted to epitope prediction and a small gene containing three antigenic regions was constructed and inserted in pET28a. Recombinant *Leishmania*-LACK was produced and used as an immunogen in BALB/c mice for mAb production. The capacity of the anti-LACK mAb to recognize native *Leishmania*-LACK was assayed by Western blotting and IHQ technique, using soluble antigens and histologic sections of skin biopsies from hamsters experimentally infected with *Leishmania (Leishmania) amazonensis, L. braziliensis* and *Leishmania* (*Viannia*) *guyanensis,* main causer parasites of CL in Brazil. In a next step, IHC anti-LACK was validated on skin lesion samples from 105 patients with suspected CL, attending the outpatient clinic of the Municipal Polyclinic of Teófilo Otoni between 2019 and 2020, having PCR as reference test. The performance of IHC anti-LACK was compared to direct examination (DE) and histopathological (HE). The anti-LACK mAb successfully recognized native LACK in soluble antigens and detected amastigotes of the three *Leishmania* spp. in histological sections from experimentally infected hamsters. Moreover, IHC anti-LACK presented sensitivity of 58.2% (CI95%: 45.0 – 70.3), specificity of 98% (CI95%: 89.5 – 99.7), and accuracy of 77.1% (CI95%: 68.2 – 84.1), higher than presented by DE and HE techniques, but there was no significant statistical differences. In a cross-table analysis, the IHQ anti-LACK presented Kappa index of 0.57 (CI95%: 0.40-0.74) and 0.62 (CI95%: 0.456 – 0.787) with the results from DE and HE, respectively. In this initial study the IHC anti-LACK demonstrated applicability for CL diagnosis and further improvement can will enhance diagnostic performance of the IHQ anti-LACK technique.

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