eP076
ePoster Viewing
Lyme borreliosis

COMPARISON OF A CELL-BASED SPIROFIND ASSAY WITH CLASSICAL SEROLOGY FOR THE DIAGNOSIS OF ACUTE LYME BORRELIOSIS

M. Lupse[1], M. Oosting[2], M. Flonta[3], O. Daraban[3], J.W.M. Van der Meer[2], M.G. Netea[2], L.A.B. Joosten[2], B.J. Kullberg[2]

[1]Infectious Diseases, Iuliu Hatieganu Medicine and Pharmacy University, Cluj, Romania ; [2]Internal Medicine, Radboud University Medical Centre, Nijmegen, Netherlands ; [3]infectious diseases, Iuliu Hatieganu" Medicine and Pharmacy University, Cluj, Romania

Background. Lyme borreliosis is the most prevalent tick-borne disease in Europe, causing cutaneous, neurologic and rheumatologic signs. Serology (two-tiered Elisa/immunoblot) and molecular tests (PCR) are the mainstay of laboratory diagnostic for Lyme disease, but sensitivity and specificity of these tests are not optimal. Recently, a cell-based immunological test (SpiroFind) based on *Borrelia*-specific induction of proinflammatory cytokines has been proposed for the diagnosis of the disease. There are currently no studies that compared the cellular- and humoral-based assays for the diagnosis of Lyme disease.

Objective: The goal of the present study was to compare a cell-based assay with the standard serology in patients with erythema migrans (EM), the most prevalent manifestation of early Lyme borreliosis.

Methods: A prospective clinical study was performed in Cluj county, Romania. Fifty-four adult patients with acute EM (physician-confirmed and photographically documented) and 19 adults with a confirmed tick bite but without EM or any other manifestation of the disease were enrolled into the study in June-August 2013. At baseline, both SpiroFind and serology were performed in both groups of patients, while in the EM-positive patients, both diagnostic tests were repeated at 2 weeks and 6 weeks later. The SpiroFind assay is based on the cytokine production capacity of PBMCs of an individual after exposure to heat-killed *Borrelia* organisms (Boulder Diagnostics, Mellrichstadt, Germany). Serological testing was performed by using Mikrogen recomLine IgM and IgG.

Results: At the time of the first visit, 26/55 (47%) of EM-positive patients were positive for the SpiroFind test, increasing to 76% at 6 weeks. At first visit, only 21/55 (38%) were positive for IgM antibodies and 5% were positive for IgG antibodies. The false positive rate of the SpiroFind test in individuals presenting with tick bites without EM was 11%, which was identical to IgM serology (11%). IgG antibodies directed against *Borrelia* antigens were found in 5% of the controls.
Conclusions: This is the first proof-of-principle clinical study of a novel cell-based test for the diagnosis of acute Lyme borreliosis. The SpiroFind assay was more sensitive than IgM and IgG serology for the identification of patients with acute Lyme borreliosis at the time of presentation with EM. The false positive rate of the SpiroFind cellular test was comparable to that of IgM/IgG antibodies. The clinical study will be continued until 1 year after diagnosis, and future clinical studies are needed to confirm these first results and to assess the therapeutic value of cell-based assays for Lyme borreliosis.