

## **Prospective Study of Serologic Tests for Lyme Disease**

Steere AC, McHugh G, Damle N, Sikand VK

Center for Immunology and Inflammatory Diseases, Division of Rheumatology, Allergy and Immunology, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA.

**BACKGROUND:** Tests to determine serum antibody levels-the 2-tier sonicate immunoglobulin M (IgM) and immunoglobulin G (IgG) enzyme-linked immunosorbent assay (ELISA) and Western blot method or the IgG of the variable major protein-like sequence-expressed (VlsE) sixth invariant region (C6) peptide ELISA method-are the major tests available for support of the diagnosis of Lyme disease. However, these tests have not been assessed prospectively.

**METHODS:** We used these tests prospectively to determine serologic responses in 134 patients with various manifestations of Lyme disease, 89 patients with other illnesses (with or without a history of Lyme disease), and 136 healthy subjects from areas of endemicity and areas in which the infection was not endemic.

**RESULTS:** With 2-tier tests and the C6 peptide ELISA, only approximately one-third of 76 patients with erythema migrans had results that were positive for IgM or IgG seroreactivity with *Borrelia burgdorferi* in acute-phase samples. During convalescence, 3-4 weeks later, almost two-thirds of patients had seroreactivity with the spirochete *B. burgdorferi*. The frequencies of seroreactivity were significantly greater among patients with spirochetal dissemination than they were among those who lacked evidence of disseminated disease. Of the 44 patients with Lyme disease who had neurologic, heart, or joint involvement, all had positive C6 peptide ELISA results, 42 had IgG responses with 2-tier tests, and 2 patients with facial palsy had only IgM responses. However, among the control groups, the IgG Western blot was slightly more specific than the C6 peptide ELISA. The differences between the 2 test systems (2-tier testing and C6 peptide ELISA) with respect to sensitivity and specificity were not statistically significant.

**CONCLUSIONS:** Except in patients with erythema migrans, both test systems were sensitive for support of the diagnosis of Lyme disease. However, with current methods, 2-tier testing was associated with slightly better specificity.

PMID: 18532885 [PubMed - indexed for MEDLINE]