Effect of Borrelia burgdorferi Genotype on the Sensitivity of C6 and 2-Tier Testing in North American Patients with Culture-Confirmed Lyme Disease.

Abstract:

Background. \char64nbsp; A potential concern with any serologic test to detect antibodies to Borrelia burgdorferi is whether the epitopes incorporated in the test provide sufficient cross-reactivity to detect infection with all of the pathogenic strains of the species. This is a particular concern for the C6 test, which is based on reactivity to a single peptide. Methods. @nbsp; C6 testing and 2-tier testing were performed on acute-phase serum samples obtained from >158 patients with erythema migrans for whom the genotype of the borrelial isolate was defined on the basis of an analysis of the 16S-23S ribosomal DNA spacer region and/or on the genetic variation of the outer surface protein C gene (ospC). The sonicated whole cell-based enzyme-linked immunosorbent assay, the immunoblots used in the 2-tier testing, and the C6 assay all used antigens from B. burgdorferi sensu stricto strain B31. Results. @nbsp; The sensitivity of C6 testing (69.5%) was greater than that of 2-tier testing (38.9%) ([Formula: see text]); the difference in sensitivity, however, was statistically significant only for patients infected with 2 of the 3 ribosomal spacer type-defined genotypes. The lower sensitivity of 2-tier testing was attributable to the low sensitivity of the immunoblot tests, rather than the first-tier enzyme-linked immunosorbent assay. There was also a trend for the sensitivity of 2-tier testing to vary according to the ospC genotype for the 14 genotypes represented in the study ([Formula: see text]); this relationship was not observed with C6 testing. Conclusions. @nbsp; Lack of sensitivity of the C6 test because of strain diversity seems less likely to be a limitation of this serologic test, compared with 2-tier testing in North American patients with early Lyme disease.