Cost-Effectiveness of Peptide-Antigen Immunoassays for Lyme Disease

To the Editor—I read with interest the article by Bacon et al. [1], regarding the use of a 26-aa segment of VlsE, C6, and a 10-aa segment of OspC, pepC10, in kinetic ELISAs for the diagnosis of Lyme disease. These peptide-antigen immunoassays appeared to be sensitive for most clinical presentations of Lyme disease and, moreover, demonstrated 99% specificity. For the detection of early Lyme disease, the immunoassay combination of C6 and pepC10 appeared to be significantly more sensitive than did a 2-tiered approach consisting of a whole-cell VIDAS ELISA followed by Western-blot confirmation of results that were positive or equivocal by ELISA. However, Bacon et al. did not demonstrate the superiority of their peptide-antigen assays to the VIDAS ELISA as a stand-alone test. This omission may be significant if the lack of sensitivity of the 2-tiered method for the detection of early Lyme disease is actually due to the Western-blot component. A prospective study by Trevejo et al. [2] had suggested that, for the detection of early Lyme disease, the Western-blot technique may be less sensitive than the VIDAS ELISA and had advised—in accordance with previous guidance by Dressler et al. [3]—that the Western blot be used as an adjunctive test in the setting of results that were equivocal by ELISA. In addition, 2 previous studies [4, 5], comparing whole-cell enzyme immunoassays to VlsE1-based ELISAs for the diagnosis of Lyme disease, had demonstrated no significant difference in sensitivity.

The cost associated with diagnostic testing using C6 peptide alone has been quoted, by one reference laboratory [6], as $160.00, whereas the cost of a whole-cell ELISA is typically half that amount [7]. It is likely that the use of pepC10 and C6 in combination will add to the cost of the immunoassay. Despite these costs, individuals exposed to European species and strains of Borrelia burgdorferi sensu lato may benefit from the C6-peptide-only immunoassay, because this antigen is highly conserved among B. burgdorferi sensu stricto, B. garinii, and B. afzelii [8]. In North America, the main drawback to whole-cell ELISAS has been their limited specificity [9]. If the VIDAS ELISA is as sensitive as the above-mentioned peptide-antigen assays, then one may consider an alternative approach: the use of these highly specific peptide-antigen assays to confirm results that are positive or equivocal by VIDAS ELISA. Given that most serology testing for Lyme disease is ordered in a setting of low pretest risk (<10%) [10], the vast majority of tests will be negative; therefore, it is possible that it will be more cost-effective to use the immunoassay combination C6 and pepC10 to confirm results that are positive or equivocal by whole-cell ELISA, rather than using it for every patient. Additional data on the performance of the VIDAS ELISA in Bacon et al.’s study population would be useful in the determination of the feasibility of this alternative approach.

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References