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A rapid ELISA for the diagnosis of MB leprosy based on complementary detection of antibodies against a novel protein-glycolipid conjugate

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Abstract

Despite the widespread use of multidrug therapy for treatment, delays in clinical recognition and under-reporting of leprosy indicate that Mycobacterium leprae transmission is continuing. Thus, leprosy is likely to persist as a significant burden on health systems in many regions. In this study, we combined 2 previously characterized leprosy antigens, leprosy IDR1 diagnostic-1 (LID-1) and ND-O, into the single fusion complex (ND-O-LID) and determined the serum antibody responses of leprosy patients from Colombia and the Philippines. Following confirmation that antibodies recognized each component within the conjugate, we assessed the performance of a rapid enzyme-linked immunosorbent assay (ELISA) system (Leprosy Detect\textsuperscript{TM} fast ELISA; InBizos International, Inc., Seattle, WA, USA) based on ND-O-LID capable of generating results within 1.5 hours of sample addition. We found ELISA results correlated with the bacteriological index and Ridley–Jopling categorization, with lepromatous leprosy patients having the highest responses, while those of borderline tuberculoid patients were lower. Multibacillary (MB) leprosy patients were distinguished with a high degree of sensitivity (95.7%) and specificity (93.2%), suggesting that this ELISA could potentially replace invasive and insensitive skin slit smear procedures that require expert microscopic examinations. Due to the speed and robustness of this assay, we believe this is an excellent tool for detecting MB leprosy patients in a simple and highly-quantitative manner.

Keywords

Leprosy; Diagnosis; Mycobacteria; Serology

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