Comparison of ML Flow and anti-PGL-I ELISA serological tests in leprosy endemic and no endemic areas

ABSTRACT
This work is a descriptive and exploratory study which correlates clinical, epidemiologic and laboratorial data to anti-PGL-I ELISA and ML Flow serologic tests results, in leprosy-endemic and non-endemic areas. It was carried out from March 2006 to December 2006 at a reference service in Sanitary Dermatology in the city of Belo Horizonte, Minas Gerais, Brazil, and at Internal Medicine Service of Del Salvador Hospital in Santiago, Chile. Enrolled population included 60 newly detected leprosy patients and others (188), such as patients with hepatitis, acquired immunodeficiency (AIDS), tropical infectious diseases and inflammatory and auto-immune diseases. For comparison, 102 healthy subjects in leprosy-endemic and non-endemic areas were also recruited. ML Flow serologic test was registered both qualitatively (positive or negative) and semi-quantitatively (0, 1+, 2+, 3+, 4+). Anti-PGL-I ELISA serologic test was performed with the same antigen used in ML Flow test (NP-P-BSA); Cut-off values were determined by two methods: ROC curve (≥ 0.157) and mean + 3 standard deviations (≥ 0.251). None of healthy controls in non-endemic area had positive ML Flow test result. ELISA test was positive in 4 controls when Cut-off of 0.157 was used and in 3 ones with Cut-off of 0.251. In leprosy-endemic area, seropositivity in each group was as follows: 70% in leprosy, 7.2% in hepatitis, 3.4% in AIDS, 11.1% in tuberculosis, 20% in tropical infectious diseases, 33.4% in inflammatory and auto-immune diseases and 6.9% in controls. Among leprosy patients, 53.3% and 46.7% had positive ELISA test result with Cut-off of 0.157 and 0.251, respectively. Positive results were observed in control (6.9% and 4.2%) and tuberculosis groups (10.7%) with these Cut-off values. Two independent ML Flow readings had only one discordant case among 351 subjects tested, what suggest a high confiability of test interpretation. Comparison between ML Flow and ELISA tests showed kappa indexes of 0.628 (substantial concordance) and 0.585 (moderate concordance) with Cut-off of 0.157 and 0.251, respectively. Among leprosy patients, kappa indexes were 0.685 and 0.545, respectively. Analysis of association between semi-quantitative ML Flow and ELISA results revealed a positive correlation. Thus, (1) there is a concordance (moderate to substantial) between available tests on detection of antibodies anti-PGL-I in leprosy patients; (2) both test had a similar behavior in quantitative detection of anti-PGL-I antibodies.

KEY WORDS
Leprosy; serology; PGL-I; ELISA; ML Flow