

ADVERSE DRUG REACTIONS, INCLUDING SJS, TEN

PROSPECTIVE HLA-B*13:01 SCREENING TO PREVENT DAPSONE HYPERSENSITIVITY SYNDROME

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Background: Dapsone hypersensitivity syndrome (DHS), a life-threatening condition, is the most serious adverse reaction associated with dapsone administration and one of the major causes of death in leprosy patients. Although the HLA-B*13:01 polymorphism has been identified as the genetic determinant of DHS in Chinese population, until now, no studies have been found to evaluate whether prospective HLA-B*13:01 screening could prevent DHS.

Objective: This study aimed to determine the clinical efficacy of prospective HLA-B*13:01 screening to prevent DHS by excluding dapsone in the treatment of HLA-B*13:01 positive patients.

Materials and Methods: We performed a prospective cohort study from February of 2015 to April of 2018. 1,539 newly diagnosed leprosy patients who had not taken dapsone previously were enrolled from 21 provinces throughout China. HLA-B*13:01 carriers were suggested to eliminate dapsone from treatment, while all other patients received dapsone. Immunological tests were performed to distinguish DHS from leprosy reactions. Primary outcome is the incidence of DHS with screening. The historical incidence of DHS (10 DHS per 1,000 leprosy patients) was used as a control.

Results: Amongst 1,512 patients (1,026 males and 486 females, with a mean age of 43.1 years), 261 (17.3%) were identified to carry HLA-B*13:01 allele; 1,251 (82.7%) did not carry. A total of 714 adverse events in 384 patients were observed during the follow-up period. DHS did not develop in any of HLA-B*13:01 negative patients treated with dapsone, while approximately 13 patients would be expected to experience DHS, based upon the historical incidence (1.0% per year; $P = 2.05 \times 10-5$). No significant correlation was found between other adverse events and HLA-B*13:01 status.

Conclusions: Prospective screening to identify patients with an HLA-B*13:01 polymorphism before commencing leprosy treatment and eliminating dapsone from standard treatment could significantly reduce the incidence of DHS in the Chinese population.





