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Improved Clinical Evaluation of Prospective Vaccines and New Therapies against AIDS

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Our objective is to improve the design and evaluation of AIDS-related clinical trials by elimination of avoidable biases in patient selection. We propose a better stratification of prognostically identical individuals with HIV infection for controlled clinical trials.

MATERIAL

Initial laboratory data for six immunological (WBC, TC#, BC#, T4#, T8#, T4/ T8) and seven metabolic variables (uric acid, BUN, glucose, cholesterol, triglycerides, SGOT, alk. phos.) were obtained from the San Francisco Men's Health Study data base for 130 homosexual/bisexual men. Within the following 24 months, 29 HIV Ab(-) asymptomatics and 29 HIV Ab(+) asymptomatics did not develop symptoms. Thirty HIV Ab(+) ARC patients did not develop AIDS, and 42 HIV Ab(+) ARC patients progressed to AIDS.

METHODS

In a blind retrospective study, two immunobalascopy patterns were used to predict a clinical outcome for each of the 130 above subjects' after 24 months (FIGS. I and 2). Immunobalascopy is a first-generation cognitive expert system for detection, quantification, and mapping of multidimensional relational abnormalities among given immunological and metabolic variables in their total interrelatedness .[2-4]

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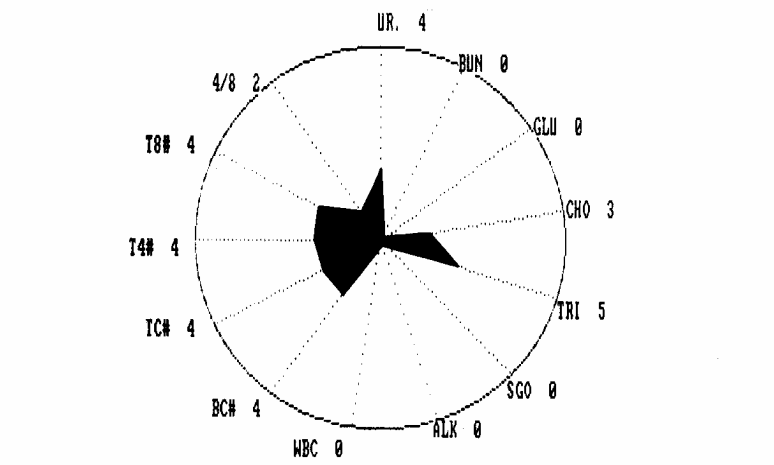

FIGURE 1. Pattern of AIDS-resistant ARC.

RESULTS

Immunobalascopy confirmed the existence of identifiable subpopulations of patients with ARC: AIDS-resistant ARC and ARC progressing to AIDS. Each subpopulation exhibits characteristic patterns of abnormal immunometabolic relationships. Statistical evaluation of predictive performance of immunometabolic patterns in early individual identification of AIDS-resistant ARC versus ARC actually progressing to AIDS demonstrated the following: sensitivity, 95%; specificity, 92%; predictive value of positive results, 84.4%; predictive value of negative results, 95.3%; and efficiency of identification, 91.5%.

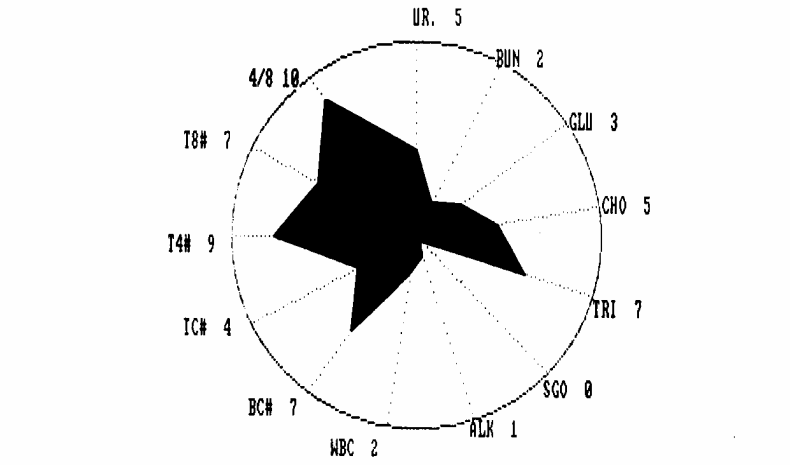

FIGURE 2. Pattern of ARC progressing to AIDS.

Results, 84.4%; predictive value of negative results, 95.3% and efficiency of identification, 91.5%.

CONCLUSIONS

Two identifiable subpopulations of ARC patients exist: AIDS-resistant ARC, and ARC actually progressing to AIDS within 24 months. Early definitive identification of individuals with ARC who are actually progressing to AIDS can be done by immunobalascopy based on routine laboratory tests. Immunobalascopy avoids the pitfalls of heterogeneity in AIDS clinical trials by identifying more prognostically homogenous patient cohorts.

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