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PRELIMINARY RESULTS ON THE SAFETY AND EFFICACY OF TRANSFER FACTOR IN LEPROSY

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Dialyzable transfer factor (TF) was prepared from the blood of lepromin (Fernandez and Mitsuda) skin test positive healthy donors. The amount of TF from approximately 7 x 10^9 lymphocytes was administered subcutaneously to each of 5 active leprosy patients in 36 divided doses over a 12 week period. Four of the patients had polar lepromatous leprosy (LL) and in each, histologically confirmed reversal reactions occurred and there was a significantly enhanced rate of clearing of M. leprae from the skin as evidenced by routine skin scrapings in comparison to a group of LL patients treated routinely with dapsone. In each LL patient the reversal reaction reached peak intensity at approximately the 8th week of TF, after TF from approximately 4.7 x 10^9 lymphocytes had been administered, and thereafter subsided in intensity despite the continuation of TF injections. In none of the LL patients (3 of whom were studied partially and 1 of whom was studied intensively) were significant changes noted in immunologic responses to armadillo derived M. leprae in vitro during or after TF.

One patient with borderline leprosy (BB/BL) was treated with TF preparations identical to two of the four LL patient. This borderline patient unexpectedly showed no clinical or histologic evidence of a reversal reaction and the rate of bacterial clearing on routine skin scrapings was no faster than that expected with dapsone alone. On the other hand, this borderline patient developed a positive tuberculin skin test and a positive lymphocyte blast transformation test to PPD during therapy with TF (several of the donors of blood for the TF were known to be PPD skin test positive and the patient was negative before TF) and in contrast to the lack of clinical response, developed transient in vitro immunologic responses to armadillo derived M. leprae as evidenced by positive lymphocyte blast transformation and suggestive indirect migration inhibitory factor assays. In all five patients, multiple tests for toxicity of TF were all negative.

On purely empirical grounds, these preliminary findings indicate that TF from lepromin skin test positive donors is effective in enhancing bacterial clearing from the skin of lepromatous leprosy patients and that it can be administered under these conditions with reasonable safety. Questions as to its mechanism of action, specificity, etc., remain to be answered. The observations that TF induced reversal reactions appear to subside in intensity in LL patients despite continued TF injections, and that the borderline patient who might be expected to have the most severe TF induced reversal reaction, in fact, had none are of interest. These observations may suggest that in addition to a relative lack of M. leprae responsive T lymphocytes, active control or feedback mechanisms which operate in leprosy to inhibit the expression of cell-mediated immune responses to M. leprae may be of major significance in the clinical manifestations of the disease.