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A double-blind, placebo-controlled trial of intravenous immunoglobulin therapy in patients with chronic fatigue syndrome.

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Abstract

PURPOSE: The chronic fatigue syndrome (CFS) is characterized by profound fatigue, neuropsychiatric dysfunction, and frequent abnormalities in cell-mediated immunity. No effective therapy is known.

PATIENTS AND METHODS: Forty-nine patients (40 with abnormal cell-mediated immunity) participated in a randomized, double-blind, placebo-controlled trial to determine the effectiveness of high-dose intravenously administered immunoglobulin G. The patients received three intravenous infusions of a placebo solution or immunoglobulin at a dose of 2 g/kg/month. Assessment of the severity of symptoms and associated disability, both before and after treatment, was completed at detailed interviews by a physician and psychiatrist, who were unaware of the treatment status. In addition, any change in physical symptoms and functional capacity was recorded using visual analogue scales, while changes in psychologic morbidity were assessed using patient-rated indices of depression. Cell-mediated immunity was evaluated by T-cell subset analysis, delayed-type hypersensitivity skin testing, and lymphocyte transformation with phytohemagglutinin.

RESULTS: At the interview conducted by the physician 3 months after the final infusion, 10 of 23 (43%) immunoglobulin recipients and three of the 26 (12%) placebo recipients were assessed as having responded with a substantial reduction in their symptoms and recommencement of work, leisure, and social activities. The patients designated as having responded had improvement in physical, psychologic, and immunologic measures (p less than 0.01 for each).

CONCLUSION: Immunomodulatory treatment with immunoglobulin is effective in a significant number of patients with CFS, a finding that supports the concept that an immunologic disturbance may be important in the pathogenesis of this disorder.

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Publication Types, MeSH Terms, Substances

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