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High-dose immunoglobulin therapy in sporadic inclusion body myositis: a double-blind, placebo-controlled study.

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Abstract

Sporadic inclusion body myositis (s-IBM) is an acquired inflammatory muscle disease of unknown cause. In general, s-IBM presents with slowly progressive, asymmetric weakness, and atrophy of skeletal muscle. There is a mild transitory or nil responsiveness to standard immunosuppressive treatment. A controlled cross-over study of 22 s-IBM patients over 3 months showed a partial improvement in those treated with high-dose intravenous immunoglobulin therapy (IVIG) versus placebo. The present study included 22 patients aged 32-75 years and with a mean duration of disease of 5.2+/-3.6 years. They were randomized by a double-blind, placebo-controlled, cross-over design to monthly infusions of 2 g/kg bodyweight IVIG or to placebo for 6 months each, followed by the alternative treatment. After 6 and 12 months the response to treatment was evaluated, using a modified Medical Research Council scale, Neuromuscular Symptom Score (NSS), the patient's own assessment of improvement, arm outstretched time, and electromyography. No serious side effects were seen, in particular no viral infection and no major cardiac or neurological complications. Overall there was no progression of the disease in 90% of patients, unlike that which might have been expected in untreated patients. A mild and significant improvement (11%) in clinical symptoms was found using NSS, but not with other test procedures. There was a trend to mild improvement in treated patients when using other tests. Individual responses to treatment was heterogeneous. The validity of this study may be reduced by mismatch of groups with regard to age at onset and variability in disease expression. The findings of this study largely confirm those of a previous IVIG trial. Treatment with IVIG may be mildly effective in s-IBM by preventing disease progression or inducing mild improvement. Long-term studies are needed to evaluate further the benefit of IVIG therapy in s-IBM.

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