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Neurology. 1997 Mar;48(3):712-6.

Treatment of inclusion-body myositis with IVIg: a double-blind, placebo-controlled study.

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Comment in:

Neurology. 1997 Mar;48(3):567-8.

We randomized 19 patients with inclusion-body myositis (IBM) to a double-blind, placebo-controlled, crossover study using monthly infusions of 2 g/kg intravenous immunoglobulin (IVIg) or placebo for 3 months. Patients crossed over to the alternate treatment after a washout period. We evaluated responses at baseline and at the end of each treatment period using expanded (0-10) MRC scales, the Maximum Voluntary Isometric Contraction (MVIC) method, symptom and disability scores, and quantitative swallowing studies. We calculated the differences in scores between IVIg and placebo from baseline to end of treatment. Of the 19 patients, 9 (mean age, 61.2 years; mean disease duration, 5.6 years) were randomized to IVIg and 10 (mean age, 66.1 years; mean disease duration, 7.4 years) to placebo. During IVIg the patients gained a mean of 4.2 (-16 to +39.8) MRC points, and during placebo lost 2.7 (-10 to +8) points ($p < 0.1$). These gains were not significant. Similar results were obtained with the MRC and MVIC scores when the patients crossed to the alternate treatment. Six patients had a functionally important improvement by more than 10 MRC points that declined when crossed over to placebo. Limb-by-limb analysis demonstrated that during IVIg the muscle strength in 39% of the lower extremity limbs significantly increased compared with placebo ($p < 0.05$), while a simultaneous decrease in 28% of other limbs was detected. The clinical importance of these minor gains is unclear. The duration of swallowing functions measured in seconds with ultrasound improved statistically in the IVIg-randomized patients ($p < 0.05$) compared with placebo. Although the study did not establish efficacy of IVIg, possibly because of the small sample size, the drug induced functionally important improvement in 6 (28%) of the 19 patients. Whether the modest gains noted in certain muscle groups justify the high cost of trying IVIg in IBM patients at a given stage of the disease remains unclear.

PMID: 9065553 [PubMed - indexed for MEDLINE]

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