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# Early Treatment of Clinically Isolated Syndrome Delays Disability Progression

**B**OSTON—Initiating treatment with interferon beta-1b at the time of the first presentation of multiple sclerosis (MS) delays the build-up of further disease activity, but it was unknown whether this would alter disease progression, according to a presentation of the latest data from the Betaseron in Newly Emerging Multiple Sclerosis for Initial Treatment (BENEFIT) study by Mark Freedman, MD, and colleagues. Dr. Freedman presented their findings at the 59th Annual Meeting of the American Academy of Neurology.

“Early treatment with interferon beta-1b decreased the risk of Expanded Disability Status Scale (EDSS) progression by 40% over 3 years compared to delayed treatment of up to 24 months,” observed Dr. Freedman, Director of the Multiple Sclerosis Research Unit, University of Ottawa, Ontario, Canada.

The BENEFIT trial is a randomized, double-blind, placebo-controlled, multicenter study of the effectiveness of interferon beta-1b in preventing patients with a clinically isolated syndrome (CIS) from developing MS. To enroll, patients with a CIS had to have at least two T2 lesions on brain MRI. Patients received either interferon beta-1b 250 mcg or placebo for 24 months or until the development of clinically definite MS. After 2 years, 45% of the placebo-treated patients developed MS.

Dr. Freedman presented the 12 month results of the follow-up phase of the BENEFIT study, in which patients who had received placebo and had not yet had a second attack in more than 24 months were offered treatment with the active drug. Of the original 176 placebo-treated patients who entered the study, 143 (81%) completed an additional 12

months. At the end of 3 years, only 16% of the patients continuously treated with interferon beta-1b had shown evidence of progression of disability compared to 24% of patients in the placebo/interferon beta-1b group, a 40% risk reduction. In addition, early versus deferred treatment with interferon beta-1b significantly reduced relapse rate and MRI activity (new or enlarging T2 or gadolinium enhancing lesions).

Dr. Freedman observed, “These findings support the value of early treatment with interferon, even after the very first clinical presentation of demyelinating disease.”

Gilles Edan, MD, Professor at the Faculty of Medicine, University of Rennes, France, presented data on a subset of patients from the BENEFIT study who had a CIS but did not develop clinically definite MS. These ‘inactive’ patients had no relapse,

progression of EDSS, or new or enlarging T2 or gadolinium enhancing lesions on T1 weighted MRI. Only 12 of the 166 (7.2%) placebo-treated patients fulfilled this criteria. At the end of two years, eight patients began treatment with interferon beta-1b while four patients continued treatment with placebo. At three years, one patient dropped out of the study. Of the remaining 11 patients, none had developed clinically definite MS, but two had developed MS by McDonald criteria. Predictive factors for ‘inactivity’ were older age at presentation (36.8 versus 30 years), lack of oligoclonal bands in CSF (44% versus 15%), and nine or fewer T2 lesions on screening MRI (58% versus 28%). These findings may provide guidance in deciding which CIS patients should receive early treatment.

**NR**

—Andrew Wilner, MD