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Betaferon® in early relapsing-remitting multiple sclerosis surveillance trial (BEST): A combined analysis of patients from Asia completing 2 years of treatment

[1]KW Lee and the BEST Study Group of Korea, [2]J Kira and the BEST Study Group of Japan, [3]CP Tsai, [4]T Umapathi, [5]C Meier, [6]L Kappos as Chair of the BEST Study Steering Committee

[1]Seoul National University Hospital, Seoul, Korea; [2]Kyushu University, Fukuoka, Japan; [3]Taipei Veterans General Hospital, Taipei, Taiwan; [4]National Neurological Institute, Singapore; [5]Bayer Schering Pharma AG Berlin, Germany; [6]University Hospital, Department of Neurology, Outpatient Clinic Neurology-Neurosurgery, Basel, Switzerland

Background: IFNB-1b has regulatory approval for use as treatment for relapsing-remitting multiple sclerosis (RRMS) and secondary progressive MS, and for patients with a single demyelinating event, based on results of randomized controlled trials. Initiating treatment at a very early stage of the disease course can be beneficial[1]; however, reports on long-term IFNB-1b-treatment in regular clinical use away from specialized MS centers are limited.

Objective: To investigate the long-term outcomes of early interferon beta (IFNB)-1b treatment in a combined subgroup analysis of Betaferon®/Betaseron® in Early relapsing-remitting multiple sclerosis Surveillance Trial (BEST) study patients from Japan, Korea, Singapore, and Taiwan with early-stage RRMS.

Methods: BEST is a large-scale, prospective, 5-year, observational trial of patients with early RRMS from 31 countries, receiving IFNB-1b 250 μg subcutaneously every other day. Parameters collected every 6 months include Expanded Disability Status Scale (EDSS) scores, relapse assessments, and health-related quality of life (HRQoL) as determined by the Functional Assessment of MS-Total Score (FAMS-TS) and EuroQol-5 Dimensional questionnaire (EQ-5D).

Results: By January 2006, 132 patients were recruited from Japan, Korea, Singapore, and Taiwan. Baseline descriptions of patients who continued treatment over 2 years are provided in Table 1. In total, 57.6% of patients continued treatment over 2 years, 83.3% had at least one visit after baseline, and 25.0% were confirmed study dropouts. Mean (±SD) duration of MS since first documented clinical event was 2.50 years (±4.05). Mean EDSS at baseline was 2.43 (±1.52). After 2 years of treatment, 88.2% of patients were progression-free. The mean annualized relapse rate in patients treated with IFNB-1b for over 2 years decreased from 0.96 before treatment to 0.39 after treatment (a reduction of 59.4%), as shown in Figure 1. The proportion of patients progression-free *and* relapse-free, or with reduction in relapse rate versus pre-baseline was 74.7%. The mean (SD, median) change in FAM-TS from baseline to 2 years was 8.8 (n=61, 32.2, 2.0) for all patients, 6.7 (n=19, 33.6, 2.0) for those with improved EDSS, 10.0 (n=35, 27.9, 6.0) for those with stable EDSS, and 8.4 (n=7, 50.4, -1.2) for those with progressed EDSS. The mean (SD, median) change in EQ-5D from baseline to 2 years was 0.067 (n=60, 0.385, 0.0) for all patients, 0.134 (n=19, 0.448, 0.0) for those with improved EDSS, 0.079 (n=34, 0.325, 0.0) for those with stable EDSS, and -0.171 (n=7, 0.441, 0.0) for those with progressed EDSS. No new or unexpected adverse events were observed.

Conclusions: Continuing IFNB-1b-treatment over 2 years is associated with reduced EDSS progression and relapse rate, and with stable HRQoL parameters in patients with RRMS from Japan, Korea, Singapore, and Taiwan.

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Table 1: Baseline description of patients from Asia in the BEST study

Baseline description	Patients who continued treatment over 2 years n=76	Confirmed dropouts n=33
Mean age at baseline, years (SD)	37.1 (13.4)	37.1 (11.1)
Female to male ratio (%)	57:43	82:18
Mean duration of MS since first documented clinical event in years (SD)	2.50 (4.04)	3.04 (3.12)
Mean EDSS at baseline (SD)	2.43 (1.52)	2.42(1.41)
Percentage of patients with baseline EDSS ≥3.0	28.9	39.4
Mean number of relapses within the last 2 years prior to treatment (SD)*	2.12 (1.37)	2.38 (1.93)
Percentage of patients with increase in disability within the last 2 years (EDSS change ≥1.0)	28.9	30.3
Cranial MRI available (%)	93.2	84.8
Enhancing lesions with contrast medium (%)	45.3	34.6

*According to clinical documentation by investigator at baseline
SD = standard deviation; MS = multiple sclerosis; EDSS = Expanded Disability Status Scale; MRI = magnetic resonance imaging

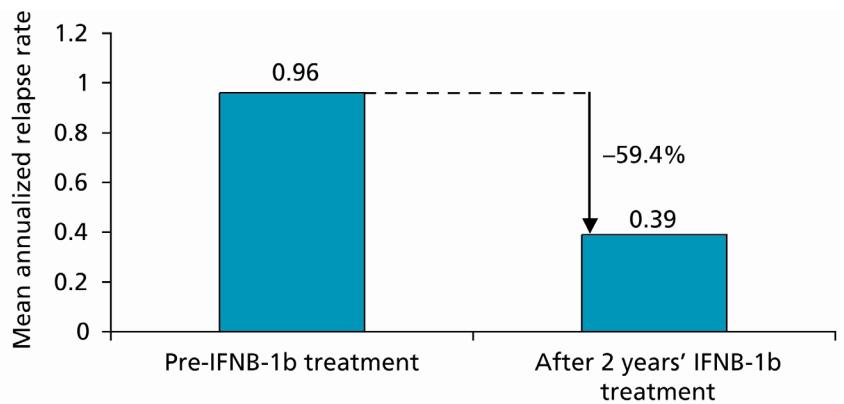

Figure 1. Reduction in the mean relapse rate after 2 years' treatment with IFNB-1b.

Reference

1. Kappos L, Freedman M, Polman C, *et al*. Effect of early versus delayed interferon beta-1b treatment on disability after a first clinical event suggestive of multiple sclerosis: a 3-year follow-up analysis of the BENEFIT study. *Lancet* 2007; 370:389-97.