Background: Multiple sclerosis (MS) is a chronic disease that spans decades, necessitating long-term therapy. Treatment tolerability may affect adherence, influencing long-term outcomes. Some safety and tolerability data reported in the interferon beta-1b (IFNβ-1b) treatment arm of key clinical trials are reviewed. Objectives: To examine the safety of IFNβ-1b (Betaseron) 250 μg in short- and long-term clinical trials in MS. Methods: Adverse events (AEs) from the BENEFIT, BEYOND, and 16-Year Long-Term Follow-Up (LTF) study databases are summarized using descriptive statistics. BENEFIT explored the effects of IFNβ-1b in patients with a first event suggestive of MS. BEYOND had IFNβ-1b and glatiramer acetate (GA, Copaxone) treatment arms. LTF revisited patients 16 years after initiation of the original registration trial. Results: Flu-like symptoms (FLSs) and injection site reactions (ISRs) were the most commonly reported AEs. FLSs were transient in nature and controlled with dose titration and use of nonsteroidal anti-inflammatory drugs. For example, in BENEFIT, FLSs were reduced by 70% over the first 2 years. Similarly, in BEYOND, 38% of IFNβ-1b-treated patients experienced FLSs during year 1; only 17% did after year 1. In BENEFIT, there was a 35% decline in ISR incidence from year 1 (46%) to year 2 (30%). Depression incidence was similar in IFNβ-1b and GA treatment arms in BEYOND. Thyroid measures were comparable across patient cohorts in the BENEFIT and LTF studies. Cancer prevalence was similar across treatment and placebo arms in all studies. Among patients using IFNβ-1b continuously in the 2 years prior to LTF, 10.1% experienced elevated liver transaminases versus 3.4% among those not using IFNβ-1b. This difference was of borderline significance (P = .054) and in keeping with previous reports. At LTF, mortality was lower in patients originally assigned to IFNβ-1b than to placebo (6 vs. 20 deaths). An intermediate number of deaths (9) was seen in the IFNβ-1b 50 μg group. Conclusions: AEs most common to IFNβ-1b are generally transient and of mild-to-moderate intensity. IFNβ-1b has a well-established safety profile based on long-term experience. Newer MS therapies will have to be measured against this favorable risk-benefit balance.

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