Background: The REGARD study compared the efficacy and safety of subcutaneous interferon beta-1a (IFNβ-1a; 44 g 3 times weekly) with that of glatiramer acetate (GA; 20 mg once daily) in patients with relapsing-remitting multiple sclerosis (RRMS). Overall safety was consistent with known profiles for both treatments. Injection-site pruritus, swelling, and induration were significantly more common with GA than with IFNβ-1a; injection-site erythema, pain, and bruising were similar in both groups; and “flu-like” symptoms were more common with IFNβ-1a than with GA. No unexpected, and few serious, adverse events occurred. 

Objectives: This post hoc safety analysis explored the prevalence and incidence of injection-site reactions (ISRs) in the REGARD study. 

Methods: REGARD was a 96-week, open-label, active-controlled, assessor-blinded study, in which treatment-naive patients were randomized to receive IFNβ-1a (n = 386) or GA (n = 378). Adverse-event data were spontaneously provided by the patient and/or resulted from nonleading questions by the investigator. In this post hoc analysis, data were re-examined to assess the prevalence and incidence of ISRs as a composite outcome during weeks 0–4, 4–12, 12–24, 24–48, 48–72, and 72–96. 

Results: Overall ISRs occurred in a lower proportion of patients in the IFNβ-1a group (44%) compared with the GA group (54%), and time to first ISR was longer with IFNβ-1a than with GA (40th percentile: 23.86 vs. 2.71 weeks). The difference in ISR prevalence between the GA and IFNβ-1a groups was noted to be greatest during weeks 0–4 (43% vs. 30%) and weeks 4–12 (48% vs. 35%). In general, the incidence of new ISRs was low from week 12 onward. More patients on GA withdrew from the study due to ISRs (six patients on GA vs. two patients on IFNβ-1a). 

Conclusions: In the REGARD study, ISRs occurred earlier in patients with RRMS receiving GA than in patients receiving subcutaneous IFNβ-1a. During the first 12 weeks of the study, ISRs were also more common in patients receiving GA; after 12 weeks, new ISRs occurred infrequently in both groups.

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