Methods

A retrospective review of medical records from 2001 to 2010 was performed by two trained RN data abstractors. Medical records from patients who had clinical visits with neurologists between initiation and discontinuation of IFNB treatment were reviewed for data abstraction, which ended at discontinuation of IFNB or in December of 2010, whichever came first.

Paper and electronic medical records of 696 patients who had MS diagnosis and any treatment of IFNB were reviewed for eligibility. Patients who had dual neurologic diagnoses, initiated IFNB treatment before their first visit to our clinic, had intermittent IFNB use, or participated in a drug study were excluded. Patients with relapsing-remitting MS (RRMS) or clinically isolated syndrome (CIS), were 18 years of age or older, were prescribed IFNB treatment under the care of our MS Center neurologists and had more than one clinic visit were included in this study (n=364).

Information on demographic and clinical characteristics was collected. The primary outcomes were time to first relapse, annualized relapse rate (ARR), time to EDSS progression, and duration of disease. Patients were censored if they discontinued therapy or left the clinic prior to the end of the observation period or relapse. Patients were censored at IFNB treatment failure (loss to follow-up) in this study. The data were analyzed using Cox proportional hazard regression. Individuals contributed person-time to the risk set until the occurrence of a relapse or the end of the observation period, whichever came first.

Results

Demographic and clinical characteristics as at age at MS onset, disease pattern, duration of disease, and number of relapses in the 12 months prior to IFNB initiation are presented in Table 1. The cohort had a mean baseline EDSS of 2.37 (SD= 1.13) which increased by 0.67 over the study period (mean 4.4, SD= 1.7) and 44% of the patients had at least one relapse.

Time to First Relapse

The mean ARR for the entire cohort while receiving IFNB was 0.299 (SD= 0.545). The estimated median time to first relapse on IFNB was 5.25 years. The ARR of 0.299 was significantly higher than the relapse rate observed by other investigators (ARR=0.17, p<0.05) and greater number of relapses in 12 months prior to IFNB initiation (ARR=1.44, p<0.002) were associated with increased hazard ratios for time to relapse. Whereas the ARR of 0.299 was significantly higher (p<0.001) than the average ARR of 0.17 for RRMS patients (p<0.001) who were maintained on IFNB treatment despite the occurrence of a relapse.

The mean duration of disease observed in our study is comparable to newer therapeutic agents, which in some cases carry potential risks for serious adverse events greater than that associated with IFNB.

Conclusion

IFNB was well tolerated by the patients in our study and is comparable to newer therapeutic agents, which in some cases carry potential risks for serious adverse events greater than that associated with IFNB.

The low ARR and small increase in EDSS observed are undoubtedly influenced by the low discontinuation rate of IFNB in this cohort when there was break-through disease, and would have been greater had the patients remained on IFNB despite the occurrence of breakthrough disease.

The mean time to first IFNB relapse of 5.25 years was not expected, given the consensus of some works that IFNB benefit is disease modifying.

The long-term benefit in disease control with IFNB use in patients with MS was observed in this cohort, and the large number of patients who have remained on IFNB for many years, because of the absence of clinical or imaging evidence disease activity, is extremely encouraging, demonstrating long-term benefit in disease control.

The ARR observed in our study is comparable to newer therapeutic agents, which in some cases carry potential risks for serious adverse events greater than that associated with IFNB. The ARR of 0.299 was significantly higher than the relapse rate observed by other investigators (ARR=0.17, p<0.05) and greater number of relapses in 12 months prior to IFNB initiation (ARR=1.44, p<0.002) were associated with increased hazard ratios for time to relapse.

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