MRI Activity versus Relapses as Markers of Disease Activity in SPMS: Data from Adelphi Real-World MS Disease Specific Programme and The Phase 3 EXPAND Study

G. Giovannoni[1], E. Houchen[2], L. Sobisek[2], H. Karu[3], S. Ryan[4], E. Jones[5], P. Dominguez Castro[2], V. Bezlyak[4], D. Piani-Meier[4], V. de las Heras[4], C. Lines[4]

[1]Blizard Institute, Barts and the London School of Medicine and Dentistry, Queen Mary University of London, London, United Kingdom, [2]Novartis Ireland Limited, Dublin, Ireland, [3]Novartis Healthcare Pvt. Ltd., Hyderabad, India, [4]Novartis Pharma AG, Basel, Switzerland, [5]Adelphi Real World, Manchester, United Kingdom

OBJECTIVE

Evaluate the contribution of MRI activity/relapses in defining disease activity in SPMS patients by analyzing Adelphi MS DSP data; understand whether active and non-active SPMS are mutually exclusive groups from EXPAND data.

BACKGROUND

SPMS is categorized as active (aSPMS) or non-active (naSPMS) based on evident disease activity.

DESIGN/METHODS

Adelphi MS DSP consisted of 37,318 MS patients (3580 SPMS patients). Patients were categorized into aSPMS (≥1 new lesion on the most recent MRI and/or ≥1 relapse in the last 12 months) and naSPMS groups. In EXPAND, disease activity was defined as presence of relapses in the 2 years prior to screening and with/without ≥1 Gd+ T1 lesion at baseline. Demographics, MRI, and relapse status were analyzed descriptively.

RESULTS

SPMS patients from Adelphi MS DSP were categorized as aSPMS (n=1889) and naSPMS (n=665). Disease activity (aSPMS) was defined based on MRI lesions (59.1%), relapse status (12.6%), and both MRI and relapse (28.3%). In the past 12 months, aSPMS (vs naSPMS) patients had a lower mean EDSS (4.6 vs 5.2), a higher proportion of patients undergoing MRI (87.7% vs 58.7%), and more MRIs/patient (1.24 vs 0.87). A greater proportion of naSPMS (vs aSPMS) patients were without treatment (45.1% vs 23.4%). In EXPAND, 52.6% of patients (n/N=866/1645) without relapse in the 2 years prior to screening and Gd+ T1 lesions at baseline were categorized under naSPMS; of these naSPMS patients who were on placebo, 52.7% experienced on-study relapse and/or MRI activity: MRI (41.8%), relapses (4.6%), and both MRI and relapse (9.2%).

CONCLUSIONS

In these studies, MRI activity appears to be a more sensitive measure of disease activity versus relapses. Even after 2 years of no relapse/MRI activity at baseline, disease activity returned in >50% of previously ‘non-active’ patients on placebo in EXPAND. Further, reduced real-world MRI monitoring decreases the chance to detect/treat new disease activity in ‘naSPMS’ patients.