Introduction

Multiple intervention beta-1a (IFN-β-1a) formulations are approved for the treatment of multiple sclerosis (MS). A shared feature of IFN-β-1a therapies is a requirement for patients to self-administer subcutaneous or intramuscular injections, although the dosage and schedule of injections varies between treatments.

Fewer injections may impact overall patient satisfaction with IFN-β-1a therapies. MOSAIC (Multi-center, Open-label, Single-arm Autoinjector Conveniene Study; NCT02260600) was a 12-week, single-arm study designed to evaluate the ease-of-use of Rebidose® (EMD Serono, Inc., Rockland, MA, USA), a ready-to-use autoinjector for IFN-β-1a subcutaneously (SC) three times weekly (1).

Inclusion criteria included patients (n=108) who had relapsing forms of MS (RMS), were ≥18 years of age, and were being treated with IFN-β-1a-SC 44 μg injected bid weekly for ≥12 weeks before screening. (2, 3)

In this exploratory analysis, the effects of deficits in neurological and cognitive status (e.g., normal status on patient-reported treatment satisfaction, disease acceptance, and quality of life (QoL)) while using the autoinjector were investigated.

Methods

Patients’ perceptions of the autoinjector were assessed using a 32-item UTQ taken after first dose and at 12 and 6 weeks.

Prespecified analyses compared 14 individual UTQ responses, as well as composite scores, for patients with normal or non-normal baseline status for 14 neuro-cognitive subtypes using a linear regression analysis of covariance (ANCOVA). Least square means (LSM) analysis was used to generate composite summary scores from 25 prescribed items in the UTQ domain to evaluate patient satisfaction and treatment preference.

Lower mean values (LMS) were considered indicative of greater satisfaction, and an LSM score of greater than or equal to 20 was considered strongly positive in all neuro-cognitive subgroups.

Baseline assessments included detailed neurological, mental, visual, and cognitive status exerts with patients categorized as having normal or non-normal status for each variable.

Cognitive status was assessed using a validated 30-item computerized cognitive battery (MindStreams®, NeuroTrax™).

Dominant-hand abnormalities were considered relevant to self-administration of treatments using the autoinjector and were assessed at baseline. Coordination, muscle tone, strength, reflex status, and sensory status of patients’ dominant hand and upper arm were all assessed as part of the dominant-hand examination.

Correction status

Precision status

Speed status

Stability status

Table 1. Baseline patient characteristics, ITT population.

Table 2. Summed UTQ total scores by normal vs non-normal baseline characteristics.

Results

Baseline patient demographic for the 108 patients included in the ITT populations are shown in Table 1. Thirty-eight patients had neurologically abnormal/dominant-hand status. Figure 1: Ten right-handed patients experienced neurologic meningeoma, and 13 had abnormal rapid alternating movements.

The endpoint assessed was the patient’s overall satisfaction with the autoinjector. Patients completed the DX36 UTQ. The overall patient satisfaction of the autoinjector was rated as ‘very satisfied’ or ‘very satisfied.’ Overall, 96% of patients rated the device positively for the ability to deliver the full injection of IFN-β-1a-SC 44 μg twice over 12 weeks.

Table 3. Effect of dominant-hand normality status on individual responses to UTQ questions.

Table 4. Change from baseline in domains of the SF-36 questionnaire: ITT population of 12 weeks.

Table 5. Change from screening in SF-36 physical health component score, role-physical, and role-emotional in the ITT population of 12 weeks.

Conclusions

After 12 weeks of using the ready-to-use autoinjector, patients’ positive opinions of the device were unaffected by the majority of baseline neuro-cognitive abnormalities assessed.

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Overall patient perceptions of the ready-to-use autoinjector were positive in all neuro-cognitive subgroups and ranged from ‘somewhat satisfied’ to ‘very satisfied.’ 96% of patients rated the device positively for the ability to deliver the full injection of IFN-β-1a-SC 44 μg twice over 12 weeks.

References


Disclosures

The authors thank Matthew Thompson, PhD of Queset, Oxford, UK (revenue from EMD Serono, Inc., Rockland, MA, USA, and Pfizer Inc, New York, NY, USA) for editorial input and analysis of the data. The authors’ roles are detailed in the author contributions and acknowledgments sections.

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*Denotes statistical significance in response between normal and non-normal patients.

aUpper extremity assessments were completed for patients’ dominant side (right- or left-handed) only, due to the likelihood that this hand/arm would be used during the injection.

bDerived from dominant upper extremity assessments.

cDerived from tone status (not shown; all patients normal), strength status, reflex status, sensory status, and coordination status for the dominant hand.

dx36

User trial questionnaire and quality of life responses in patients with multiple sclerosis by neurological and cognitive status: MOSAIC study

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