Patient injection setting preferences on an auto-injector for IFN β-1a

F Dangond,1 B Mercer2

1EMD Serono, Inc.*, Rockland, MA, USA; 2Formerly employed by EMD Serono, Inc.*, Rockland, MA, USA

Background

• Most disease-modifying drugs (DMAs) for the treatment of multiple sclerosis (MS) are self-administered by patients on a long-term basis. To achieve optimal clinical benefits, it is essential for patients to adhere to their treatment regimen.1

• The use of electronic auto-injector devices may improve patient adherence to DMAs due to improved injection tolerability and patient satisfaction.12

• An electronic auto-injector, which incorporates several features designed to improve the comfort and convenience of self-injection, has been developed for the administration of subcutaneous IFN β-1a (INTERFERON β-1a).15

• This electronic auto-injector has four injection settings that can be adjusted by patients to maximize comfort: needle insertion speed, slow, medium, or fast; injection rate (speed of fluid injection), slow, medium, or fast; injection time (time from end of fluid injection to needle retraction), 3–15 seconds; injection depth (depth of needle insertion) using a 29-gauge needle, 4, 6, 8, or 10 mm.

• The ease of use, patient acceptability and satisfaction, and functional reliability of the electronic auto-injector in patients with relapsing MS receiving IFN β-1a three times weekly (twice) were evaluated in the PERFORMS study.4

Objective

• To examine factors that may affect patient injection setting preferences in an exploratory analysis of patients who adjusted injection settings in the PERFORMS study.

Methods

Study design and treatment

• PERFORMS (ACTH103165) was a Phase IIIb, open-label, single-arm, multicenter trial conducted in the United States.

• Patients self-injected IFN β-1a, 44 µg SC thrice weekly using the electronic auto-injector.

• Training on the correct use of the device was provided on Day 1 and patients were given the device manual and written instructions.

• The baseline settings for the electronic auto-injector were a medium needle insertion speed, an injection speed of 11 seconds, and an injection depth of 8 mm.

Results

Patients

• Of the 103 patients enrolled in the PERFORMS study, 55 were included in the exploratory analysis population.

• Baseline demographics are presented in Table 1.

Assessments

• Patient satisfaction with the electronic auto-injector was evaluated by the online User Trial Questionnaire (UTQ): Part A was completed at baseline and consisted of 8 questions regarding prior medical conditions, previous injection experience, and expectations of the functional reliability of the device.

• Part B was completed in Weeks 6 and 12 and consisted of 38 questions about the patients’ experience using the electronic auto-injector. Each question on the UTQ had between 2 and 5 possible pre-specified responses, except for one question which had 10 possible responses.

• The primary outcome was to examine the final injection depth setting and body mass index (BMI) stratified by gender.

• Other endpoints included changes in needle insertion speed, injection speed, and injection time from baseline at the final recorded setting, and the impact of adjusting the comfort settings on the overall injection experience.

Statistics

• The primary outcome was analyzed using the Cochran-Mantel-Haenszel non-zero correlation test.

• Other endpoints were analyzed descriptively.

Impact of changing injection settings on overall experience

• More than half of the patients (58.2%; 32/55) felt that adjusting the injection settings improved the injection experience overall (Figure 3).

Conclusions

• Among patients who made at least 1 change to any injection setting over 12 weeks, the final injection depth did not appear to be related to BMI or gender, suggesting that individual preference may determine the final setting.

• However, these findings should be interpreted with caution due to the small size of the analysis population.

• The most common settings at study completion were the default settings. When changes were made, patients tended to increase the needle insertion and injection speeds, and decrease the injection time.

• A majority of patients rated the changes as improving the overall injection experience, supporting the value of providing adjustable injection setting options.

References


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*Affiliates of Novo Nordisk, Danmark, Denmark.