Association of neurologic deficits with preference for manual injections vs. auto-injector use

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Background

- Factors that determine user preference between manual injection versus an auto-injector for administration of disease-modifying drugs (DMDs) in relapsing multiple sclerosis (RMS) are unknown.
- Injection devices, such as auto-injectors, for the administration of DMDs may improve treatment adherence, due to better tolerability and increased patient satisfaction. 1,2
- The MOSAIC (NCT00989080) 3 and PERFORMS (NCT013028165) 4 studies gathered data in a similar manner for the injection method at the time of study entry and baseline demographic data.
- Baseline data, to include cognitive deficits, demographic data, and neurologic examination results, are assessed in this exploratory analysis to determine the association with injection method.

Objective

- Examination of baseline cognitive status, and demographic and neurologic test variables, in patients with relapsing-remitting MS (RRMS) who receive treatment either by manual injection or using an auto-injector.

Methods

- All enrolled patients from the MOSAIC and PERFORMS (12-weeks, Phase IIIb, single-arm, multicenter) trials were selected for analysis.
- Patients were eligible to enroll in MOSAIC and PERFORMS if they were aged 18–65 years with RMS and had been receiving subcutaneous (SC) interferon beta-1a (IFN β-1a), 44 µg three times weekly, for ≥12 weeks, using prefilled manual injections is prefilled syringe or the Rebiqza® (β-thal) auto-injector (EMD Serono, Inc, Rockland, MA).
- Patients who had used both methods of injection were excluded from this analysis.
- The primary endpoint of this analysis was to examine the association between patients with an abnormal, or probable abnormal, Global Cognitive Score (GCS) and their preferred method of injection (chosen prior to trial entry).

Results

- The mean (range) age of the analysis population was 46.5 (19–65) years and contained a majority (74.5%) of female patients.
- A total of 184 out of 224 patients were included in the analysis, of which 43 patients preferred the manual injection (23.4%), and 141 patients preferred the auto-injector (76.6%) (Table 1).
- Associations between demographic variables with injection preference, including age, gender, BMI, and hand dominance, demonstrated a tendency (p-value > 0.05) for older patients to use an auto-injector, but statistical significance was not achieved (Table 2).
- Examination of cognitive and neurologic function was made at baseline and included assessments of mental status, cranial nerves (including visual acuity), muscle tone, muscle strength, reflexes, sensory function, coordination (including dominant hand and arm dexterity), and gait.
- The neurologic exam consisted of 8 sections, comprising 72 items.
- There were no significant differences in understanding how to use the device or in ability to inject correctly at the end of the training session between patients who preferred manual injections and those who preferred auto-injectors (data not shown).
- There were no significant differences between GCS and visual acuity or manual dexterity.
- Association between cognitive deficit and the use of manual injections or the Rebiqza® auto-injector for the proportion of patients with an abnormal or probable abnormal result for the Attention Index Score, Executive Function Index, or Memory Index Score.
- The association between cognitive deficit and the use of manual injections and the Rebiqza® auto-injector for the proportion of patients with abnormality for visuo-spatial function, strength, coordination, tone, or sensory testing.
- The association between patients’ demographic baseline characteristics and the use of manual injections and Rebiqza® auto-injector for mean age, gender, body mass index (BMI), and proportion of right- or left-handers.

Table 1. Baseline preferred injection method.

<table>
<thead>
<tr>
<th>Study</th>
<th>Manual injection</th>
<th>Auto-injector</th>
<th>Patients not included</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOSAIC (n=217)</td>
<td>118 (54.8%)</td>
<td>99 (45.2%)</td>
<td>23 (10.7%)</td>
</tr>
<tr>
<td>PERFORMS (n=204)</td>
<td>25 (24.3%)</td>
<td>61 (59.5%)</td>
<td>17 (16.2%)</td>
</tr>
<tr>
<td>Total (n=421)</td>
<td>143</td>
<td>160</td>
<td>118</td>
</tr>
</tbody>
</table>

Table 2. Exploratory analysis population demographics.

<table>
<thead>
<tr>
<th>Manual injection (n=204)</th>
<th>Auto-injector (n=197)</th>
<th>P-value</th>
</tr>
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<tbody>
<tr>
<td>Age (mean ± SD)</td>
<td>44.1 ± 7.3</td>
<td>43.7 ± 7.3</td>
</tr>
<tr>
<td>Gender (Female %)</td>
<td>72.1</td>
<td>76.9</td>
</tr>
<tr>
<td>Body mass index (BMI)</td>
<td>27.6</td>
<td>29.9</td>
</tr>
<tr>
<td>Right-handed %</td>
<td>60.3</td>
<td>68.6</td>
</tr>
</tbody>
</table>

Conclusions

- There were no apparent associations between injection method and cognitive deficits, neurologic examination results, or demographic variables, for the sc administration of IFN β-1a when comparing a prefilled syringe manual injection and the Rebiqza® (β-thal) auto-injector.
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References


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Disclosures

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Figure 1. Cognitive endpoints.

Figure 2. Neurologic examination results.

Figure 3. Manual injection vs. auto-injector use.