Quality of Life Among Patients With Multiple Sclerosis Treated With Prolonged-Release Fampridine 10 mg Tablets Twice Daily for Walking Impairment: Post Hoc Analysis of the MOBILE Study

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INTRODUCTION

- Patients with multiple sclerosis (MS) typically have reduced health-related quality of life (HRQoL) resulting from symptoms that include mobility impairment, bowel problems, pain, sexual dysfunction, and fatigue.1

- Prolonged-release (PR) fampridine (shown as a dosedelayed extended-release tablets in the United States) is indicated for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale [EDSS] score 4.0–7.0) in Europe.2

- Recent clinical studies have demonstrated significant and clinically meaningful improvements in disease-specific HRQoL with PR-fampridine therapy compared with placebo.3

- A number of patients has been suggested as a conservative estimate clinically important difference (MCID) for identifying 12-item MS Walking Scale (MSWS-12) responders.4

- The objective of this post hoc analysis of the MOBILE trial was to evaluate the effect of PR-fampridine 10 mg tablets twice daily in patients with walking impairment stratified by the disease-specific MSWS-12 responder status.

METHODS

- MOBILE was a 24-week, randomized, double-blind, placebo-controlled, Phase 2 study to assess walking, and HRQoL, with PR-fampridine 10 mg tablets twice daily versus placebo in patients with MS (Figure 1).

- Outcome Measures

  - MS-specific patient-reported walking ability was assessed using the MSWS-12.3

  - The MSWS-12 is a 12-item questionnaire that asks patients to rate limitations of their mobility due to MS during the preceding 2 weeks on a 5-point scale (1 = no limitations; 5 = extreme limitations).

  - Generic HRQoL was assessed using the EuroQol-5 Dimensions 3-Level Instrument (EQ-5D-3L) in patients with MS with walking impairment stratified by the disease-specific MSWS-12 responder status.

- At Baseline, the PR-fampridine responders had a higher proportion of female patients and patients with EDSS ≤6.0 compared with the placebo and nonresponder groups (Table 1).

- For this analysis, patients were categorized into 3 groups:

  - Placebo (provided for reference only)

  - PR-fampridine responders: patients with a mean improvement from Baseline in MSWS-12 score ≥8 points

  - PR-fampridine nonresponders: patients with worsening, no change, or <8 points mean improvement in MSWS-12 score over 24 weeks

RESULTS

- A total of 132 patients were enrolled at multiple sites in Europe and Canada.

- 44% of patients in the PR-fampridine group versus 20% of patients in the placebo group were defined as responders based on MSWS-12 criteria (Figure 1).

- At Baseline, the PR-fampridine responders had a higher proportion of female patients and patients with EDSS ≤6.0 compared with the placebo and nonresponder groups (Table 1).

- The PR-fampridine responders also had a higher mean baseline EQ-5D utility index and VAS scores (indicating better HRQoL) versus the nonresponder and placebo groups (Table 1).

CONCLUSIONS

- For this analysis, patients were categorized into 3 groups:

- Placebo (provided for reference only)

- PR-fampridine responders: patients with a mean improvement from Baseline in MSWS-12 score ≥8 points

- PR-fampridine nonresponders: patients with worsening, no change, or <8 points mean improvement in MSWS-12 score over 24 weeks

- At Baseline, PR-fampridine responders had a higher proportion of female patients and patients with EDSS ≤6.0 or relapsing-remitting MS (RRMS) compared with the placebo and nonresponder groups.

- A higher proportion of PR-fampridine responders improved on each of the individual EQ-5D domains compared with the nonresponders (Figure 2).

- A small increase in mean improvement in the EQ-5D utility index and VAS score was observed over time in the PR-fampridine responders.

- The EQ-5D visual analog scale (VAS) score ranges from 0 (worst imagined health state) to 100 (best imagined health state).

- Generic HRQoL was assessed using the EQ-5D-5L.

- MS-specific patient-reported walking ability was assessed using the MSWS-12.

- PR-fampridine responders had a higher proportion of female patients and patients with EDSS ≤6.0 compared with the placebo and nonresponder groups.

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Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Placebo</th>
<th>PR-fampridine responders</th>
<th>PR-fampridine nonresponders</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, y</td>
<td>49.8</td>
<td>56.1</td>
<td>60.4</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) body mass index, kg²</td>
<td>25.5 (4.9)</td>
<td>26.7 (4.0)</td>
<td>26.9 (5.1)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) EDSS score</td>
<td>6.0 (1.7)</td>
<td>5.5 (1.3)</td>
<td>6.1 (1.4)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) MSWS-12 score</td>
<td>26.9 (11.1)</td>
<td>25.0 (10.7)</td>
<td>28.7 (12.3)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) TUG score</td>
<td>15.4 (6.3)</td>
<td>16.0 (6.8)</td>
<td>15.0 (6.5)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) 6MWT score</td>
<td>464 (95)</td>
<td>455 (92)</td>
<td>472 (101)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) MS-QoL scale score</td>
<td>5.4 (1.5)</td>
<td>5.6 (1.7)</td>
<td>5.4 (1.5)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) EQ-5D utility index</td>
<td>0.69 (0.27)</td>
<td>0.70 (0.29)</td>
<td>0.68 (0.27)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) EQ-5D VAS score</td>
<td>76.8 (19.7)</td>
<td>77.5 (19.7)</td>
<td>76.2 (19.7)</td>
<td></td>
</tr>
</tbody>
</table>

CONCLUSIONS

- PR-fampridine responders demonstrated greater improvement in EQ-5D utility index scores versus MSWS-12 nonresponders in the MOBILE study.

- The improvement in the utility index scores (Δ664) in the PR-fampridine responder group corresponded with the criterion for MSWS-12 responder group (Δ58–65), as suggested by a recent study that employed both distribution-based and anchor-based analyses (Δ379).5 To identify the MCID in the EQ-5D utility index scores, a threshold of 0.0415 was applied to the mean improvement in the EQ-5D utility index scores.

- At Week 24, a higher proportion of PR-fampridine responders improved on each of the individual EQ-5D domains compared with the nonresponders (Figure 3).

- Generalized improvements were observed in the mobility, self-care, and pain/discomfort EQ-5D domains in the PR-fampridine responders versus nonresponders.

Acknowledgments

This study was funded by Biogen Idec, Cambridge, MA, USA. Biogen Idec had editorial support for the preparation of this manuscript and for free medical writing assistance with the preparation of this manuscript. Writing and editorial support for this full-length manuscript were provided by Excel Scientific Solutions (Southport, CT, USA); funding was provided by Biogen Idec.

Disclosures

- No disclosures.

References


For an extensive list of references, please refer to the full publication.