Table 2. Total hospitalizations and their relationship to ALS

<table>
<thead>
<tr>
<th></th>
<th>Total hospitalizations</th>
<th>Placebo (n=139)</th>
<th>Reldesemtiv (n=234)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause</td>
<td>110</td>
<td>33 (20.8%)</td>
<td>77 (23.8%)</td>
<td></td>
</tr>
<tr>
<td>HR-ALS</td>
<td>77</td>
<td>21 (13.2%)</td>
<td>56 (17.3%)</td>
<td></td>
</tr>
<tr>
<td>HU-ALS</td>
<td>22</td>
<td>7 (4.4%)</td>
<td>15 (4.6%)</td>
<td></td>
</tr>
<tr>
<td>HI-ALS</td>
<td>7</td>
<td>3 (1.9%)</td>
<td>4 (1.2%)</td>
<td></td>
</tr>
</tbody>
</table>

*Not classified: 4

Table 3. Reasons for hospitalizations and their relationship to ALS

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Placebo (n=139)</th>
<th>Reldesemtiv (n=234)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>31</td>
<td>30</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mucous plugging</td>
<td>7</td>
<td>6</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Dysphagia</td>
<td>22</td>
<td>21</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>PEG tube</td>
<td>19</td>
<td>18</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>12</td>
<td>9</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>75</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

*Not classified: 6

Figure 1. Hospitalizations: A) total hospitalizations; B) HR-ALS hospitalizations

CONCLUSIONS

- There was no difference in first hospitalization rates between patients receiving placebo and those taking reldesemtiv.
- Dysphagia and respiratory failure were the most common SAEs that led to hospitalizations during the trial.
- The total follow-up was comparable between the 2 treatment groups, with no differences in first hospitalization rates between patients receiving placebo and those taking reldesemtiv.

DISCUSSION

- The data presented here describe general findings and summary statistics.
- Although hospitalization events are common endpoints in trials of other chronic diseases, these have rarely been systematically evaluated in ALS trials.
- Given that hospitalizations unrelated to ALS are not rare in this patient population, this study suggests that determining the relationship is worthwhile. However, even with detailed information provided to the site regarding how to categorize the events, some inconsistencies in how they were assigned were seen.
- If time to hospitalization is included as an endpoint in future clinical ALS trials, employing a formal adjudication committee with a rigorous charter and process may be needed to ensure consistency.

ACKNOWLEDGMENTS

- The study was funded by Cytokinetics, Incorporated.
- The data presented here describe general findings and summary statistics.
- There was no difference in first hospitalization rates between patients receiving placebo and those taking reldesemtiv.
- Dysphagia and respiratory failure were the most common SAEs that led to hospitalizations during the trial.
- The total follow-up was comparable between the 2 treatment groups, with no differences in first hospitalization rates between patients receiving placebo and those taking reldesemtiv.

DISCLOSURES

- No conflicts of interest.
- No potential conflict of interest to disclose.
- No personal information is stored.
- To obtain a PDF.
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- To obtain a PDF.

REFERENCE