OnabotulinumtoxinA Improves Urodynamc Parameters in Patients With Neurogenic Detrusor Overactivity

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INTRODUCTION
- Patients with spinal cord injury (SCI) on multiple sclerosis (MS) often have involuntary detrusor contractions, demonstrated on urodynamics as neuromuscular detrusor overactivity (NDO).
- NDO frequently results in urinary incontinence (UI), which greatly decreases patient quality of life (QOL).1
- Anticholinergic agents are used as first-line treatment for NDO; although many patients discontinue their use due to lack of efficacy or due to adverse effects.2

HYPOTHESIS/AIMS OF STUDY
- To evaluate urodynamc outcomes in patients with NDO treated with placebo, onabotulinumtoxinA 200U, or onabotulinumtoxinA 300U from the pooled week 6 results of 2 large, placebo-controlled, multicenter trials conducted in patients with SCI or MS.

MATERIALS AND METHODS

Study Design and Participants
- Results are presented for 2 pivotal, double-blind, randomized, placebo-controlled phase 3 studies that were identical in exclusion criteria and treatments - Study 19162-515 (NCT00131766) and study 19162-516 (NCT00451290), the DIGNITY studies
- Eligible patients had NDO due to SCI or MS with ≥14 UI episodes/week and were not adequately managed by anticholinergics.
- The primary efficacy endpoint in both studies was change from baseline in the number of incontinence episodes at week 6 following the first treatment.

RESULTS

Baseline Demographics and Disease Characteristics

Table 1. Baseline Characteristics (ITT Population)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Placebo (n=127)</th>
<th>OnabotulinumtoxinA 200U (n=120)</th>
<th>OnabotulinumtoxinA 300U (n=116)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>46.2 (13.3)</td>
<td>45.9 (13.3)</td>
<td>45.4 (13.0)</td>
</tr>
<tr>
<td>Male gender, n (%)</td>
<td>118 (46.1)</td>
<td>92 (41.5)</td>
<td>90 (38.1)</td>
</tr>
<tr>
<td>Etiology, n (%)</td>
<td>110 (45.6)</td>
<td>97 (47.2)</td>
<td>100 (42.9)</td>
</tr>
<tr>
<td>MS</td>
<td>131 (54.6)</td>
<td>120 (56.0)</td>
<td>116 (48.1)</td>
</tr>
<tr>
<td>SCI</td>
<td>110 (45.6)</td>
<td>97 (47.2)</td>
<td>100 (42.9)</td>
</tr>
<tr>
<td>Anticholinergic use, n (%)</td>
<td>140 (55.7)</td>
<td>120 (52.6)</td>
<td>119 (53.4)</td>
</tr>
<tr>
<td>CIC use, n (%)</td>
<td>139 (55.7)</td>
<td>119 (53.4)</td>
<td>117 (53.4)</td>
</tr>
<tr>
<td>Disease characteristics</td>
<td></td>
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<tr>
<td>Duration of NDO, w</td>
<td>7.7 ± 6.9</td>
<td>7.6 ± 6.6</td>
<td>7.8 ± 4.4</td>
</tr>
<tr>
<td>UI episodes/wk, n</td>
<td>31 ± 23.0</td>
<td>32 ± 21.1</td>
<td>31 ± 17.5</td>
</tr>
<tr>
<td>MCI, mL</td>
<td>253.5 ± 141.9</td>
<td>252.0 ± 151.4</td>
<td>252.4 ± 146.4</td>
</tr>
<tr>
<td>MDP during first IDC, cm H2O</td>
<td>45.2 ± 35.8</td>
<td>51.5 ± 37.3</td>
<td>40.5 ± 28.1</td>
</tr>
<tr>
<td>Volume at first IDC, mL</td>
<td>203.9 ± 155.5</td>
<td>204.3 ± 166.2</td>
<td>182.9 ± 125.9</td>
</tr>
<tr>
<td>Detrusor compliance, mL/cm H2O</td>
<td>64.2 ± 92.8</td>
<td>55.7 ± 81.4</td>
<td>54.4 ± 80.5</td>
</tr>
</tbody>
</table>

Efficacy at Week 6 (Treatment Cycle 1)

Clinical Outcomes
- Significant decreases in UI were reported by 74.0%, 85.0%, and 83.8% of patients in the placebo, onabotulinumtoxinA 200U, and onabotulinumtoxinA 300U groups, respectively (Table 2).

- In those patients who did have an IDC, MDP during first IDC was significantly decreased in both onabotulinumtoxinA dose groups compared with placebo (Figure 4).

- Volume at first IDC and detrusor compliance were significantly increased with onabotulinumtoxinA treatment compared with placebo (Figure 5).

Urodynamc
- OnabotulinumtoxinA significantly increased MCC compared with placebo (P<0.001) (Figure 1).

CONCLUSIONS

2. Shippey A et al. BJU Int. 2009;104:1447-52

REFERENCES

2. Shippey A et al. BJU Int. 2009;104:1447-52

DISCLOSURES

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