Duration and Efficacy of Repeat Salivary Gland Onabotulinum Toxin-A Injection: A Retrospective Cohort Study

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INTRODUCTION

• Sialorrhea (drooling) is common in patients with spasticity.
• Increases risk of aspiration, choking, infections.
• Oral anticholinergic treatment medications can cause systemic side effects (e.g., severe constipation).
• Onabotulinum Toxin A (BTX-A) to salivary glands can reduce drooling, with limited side effects.
• Efficacy of BTX-A lasts 2-5 months.

Goals of study:
• To determine efficacy of repeated BTX-A injections to treat sialorrhea.
• To determine safety of this approach.

METHODS

• Retrospective chart review, March 2011 – March 2012
• Patients with cerebral palsy (age < 20 yrs) who had received SEMLC injections for sialorrhea and spasticity.
• All injections done under ultrasound and E-stim guidance.
• 29 cases identified → 24 had adequate documentation.

• 15 patients had received fewer than 4 BTX-A injections, 9 patients had received more than 4 BTX-A injections.

• Outcome measure: Goals attained
  o Goals identified before injection.
  o At follow-up, goals categorized as “No Improvement,” “Some Improvement,” or “Goals Met/Exceeded.”
• Side effects recorded.
• Statistics: SPSS, independent samples t-tests.

PARTICIPANT CHARACTERISTICS

<table>
<thead>
<tr>
<th></th>
<th>&lt; 4 injections (n=13)</th>
<th>&gt; 4 injections (n=9)</th>
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<tbody>
<tr>
<td>Male: Female</td>
<td>7:6</td>
<td>3:6</td>
</tr>
<tr>
<td>Age (Y ± SD)</td>
<td>8,11 ± 5,6</td>
<td>9,8 ± 5,4</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>10 CP; 1 Anti-NMDA, 1 neurodegenerative disorder, 1 Progressive Ponto bulbar palsy</td>
<td>7 CP; 1 CHARGE syndrome, 1 idiopathic peripheral neuropathy.</td>
</tr>
<tr>
<td>Gastroesophageal reflux disease</td>
<td>8 (61.5%)</td>
<td>6 (66.6%)</td>
</tr>
<tr>
<td>Tracheostomy</td>
<td>4 (30.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Feeding Tube</td>
<td>7 (53.8%)</td>
<td>6 (66.6%)</td>
</tr>
<tr>
<td>Seizure Disorder</td>
<td>8 (61.5%)</td>
<td>3 (11.1%)</td>
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ULTRASOUND-GUIDED INJECTIONS

OUTCOMES 6 MONTHS POST-INJECTION

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<th>&lt; 4 injections</th>
<th>&gt; 4 injections</th>
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<tbody>
<tr>
<td>Goal reached</td>
<td>0%</td>
<td>67%</td>
<td>P&lt;0.05</td>
</tr>
<tr>
<td>Improvement from baseline drooling</td>
<td>33%</td>
<td>89%</td>
<td>P&lt;0.05</td>
</tr>
<tr>
<td>Mean duration of efficacy</td>
<td>2 months</td>
<td>13 months</td>
<td>P&lt;0.05</td>
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DETERMINATION OF EFFICACY

Did injections improve symptoms?

Efficacy = Goals met or exceeded.

Example goals:
• Improved ability to communicate, improved food intake, decreased frequency of aspiration pneumonias, decreased frequency of suction or bib/clothing change, increased patient hygiene.
• Length of efficacy of each injection was extended significantly with repeat injection: duration significantly longer than in prior reported research.
• No increased risk with repeated injections.

CONCLUSIONS & RECOMMENDATIONS

• Cumulative benefit to repeat salivary gland injections
• Prospective study needed to confirm these findings and identify a possible mechanism of action.