Effect of Upper Limb Botulinum Toxin Injections on Impairment, Activity, Participation, and Quality of Life Among Stroke Patients

Gilles D. Caty, MD; Christine Detrembleur, PhD; Corinne Bleyenheuft, MD; Thierry Deltombe, MD; Thierry M. Lejeune, MD

Background and Purpose—The purpose of this study was to study the effect of Botulinum toxin type A (BoNT-A) injections in spastic upper limb muscles on impairment, activity, participation and quality of life in chronic stroke patients.

Methods—BoNT-A (Dysport) was injected into several upper limb spastic muscles in a group of 20 patients. Neurological impairment (muscle tone and strength, dexterity, SIAS), activity (ABILHAND), participation (SATIS-Stroke), and quality of life (SF36) were assessed before and 2 months after the injections.

Results—BoNT-A injections improved muscle tone, but had no impact on dexterity, manual ability, social participation, and quality of life.

Conclusions—In this study, BoNT-A injections in spastic upper limbs significantly reduced neurological impairments, but had no functional impact. (Stroke. 2009;40:00-00.)

Key Words: stroke ■ arm ■ spasticity ■ Botulinum toxins

Many stroke patients present with hand disability secondary to spastic hemiparesis. This activity limitation can reduce their social participation and quality of life. Botulinum toxin type A (BoNT-A) injections are increasingly used to manage spasticity among stroke patients. Systematic reviews1 have shown that these injections effectively reduce neurological impairment. However, the functional consequences of these reductions on activity and participation remain unclear, despite the fact that functional issues are often a major focus of rehabilitation programs.2

Upper limb abilities (ICF activity domain) presented by hemiparetic patients can be divided into passive and active function. Passive functions relate to the tasks performed by the nonaffected arm or by a caregiver, whereas active functions include tasks that the subject performs with the affected limb. Even though the relationship between impairment and activity is not clear in hemiparetic spastic patients, we would logically hypothesize that a reduction in spasticity might lead to an improvement in patient activity and to a reduction in burden of care.

Very few studies2,3 have examined the effects of managing poststroke upper limb spasticity on activity, and to date no studies have comprehensively assessed active function. Consequently, Francisco4 recently stated that, to date, “... studies have not demonstrated unequivocally that Botulinum toxin injection is effective in improving function...” Additionally, no study has specifically addressed the effect of upper limb BoNT-A injections on social participation. Therefore, our aim with this stroke patient study was to investigate the effects on impairment, activity (particularly active function), and participation of BoNT-A injections in spastic upper limb muscles.

Subjects and Methods
Twenty stroke patients were enrolled in our study, which was approved by the Local Ethics Committee. All subjects provided written informed consent. Inclusion criteria were spastic arm paresis, minimal manual dexterity (Box and Block test score ≥1), and a period of greater than 6 months since the patient’s most recent stroke. Exclusion criteria included BoNT-A injection within the past 6 months, other pathologies with potential effects on manual ability, and any cognitive deficit that would prevent the completion of questionnaires. The mean subject age was 58.9±18.1 years (range:20 to 82), and interval since stroke was 45.9±57.7 months (range:7 to 252). Ongoing treatments (physical therapy and medication) remained unchanged throughout the study.

BoNT-A (500U Dysport/1 mL saline, Ipsen) was injected with EMG guidance and electrostimulation in several spastic arm muscles (Table 1). The total BoNT-A dose for each patient ranged from 400 to 1000U. Each subject was assessed by the same evaluator before and 2 months after BoNT-A injection. The ICF-based assessment set is presented in Table 2. A paired t test was used to analyze the...
modification of the parametric data and a Wilcoxon Test to analyze the modification of nonparametric data.

Results
BoNT-A treatment, which was well tolerated, reduced neurological impairment, as evidenced by the increase in SIAS values and the decrease in muscle tone (Table 3). Maximal voluntary grip and key pinch strengths did not change. The MRC grade was significantly reduced for the elbow and thumb flexors but not for other muscles. The active function of the affected arm (Box and Block and Purdue Pegboard tests), manual ability, satisfaction with social participation, and quality of life all remained unchanged.

Discussion
This study confirms the efficacy of BoNT-A injections in reducing spasticity and neurological impairment among stroke patients. However, these injections did not improve activity or participation, which is consistent with a recent systematic review.1 Certain studies claim to identify functional effects of BoNT-A injections with the Frenchay Arm Test5 or the Disability Assessment Scale (DAS)2,3 and have shown variable results.6 However, such instruments do not focus on activity and certain domains measured by the DAS (eg, pain and palmar infection) refer to impairment and not to functional upper limb abilities. The study by Brashear3 was criticized,6,7 because of its lack of clarity regarding the term “functional disability,” and because of the limited improvement recorded in a subjective and narrow band of patient disabilities. In contrast, the ABILHAND8 questionnaire assesses unimanual and bimanual daily life activities, and all functional upper limb ability (ie, both passive and active function). Another particularity of the present study is that we also include patients who exhibit minimal manual dexterity, namely subjects who should be more prone to functional improvement. Despite this inclusion criterion, no significant effect was present at the group level. It was also impossible to identify a subgroup of patients that demonstrated a positive effect in terms of functional outcome by studying the relationship between their initial impairments.
activity assessments, or clinical characteristics (ANOVA and correlation analysis). This lack of functional improvement suggests that spasticity does not necessarily contribute to limitations in respect of upper limb function. Disability may be more directly related to negative upper motor syndrome signs (eg, paresis).

The BoNT-A treatment had no impact on subject participation (SATIS-Stroke6) or on quality of life (SF36). Potential explanations for this phenomenon include a lack of improvement in the activity domain, a treatment effect that failed to meet patient expectations, a relatively short interval (2 months) between evaluations, and the fact that participation may depend on contextual factors that cannot be modified by treatment.

A specific goal should be set for each patient before BoNT-A injection. Goals targeted toward improving the impairment should be realistically attainable. Such goals could include pain relief, healing of palmar ulcers, or limb positioning improvements. A goal related to activity is far more difficult to achieve. Indeed, the present study, along with other publications,1 has failed to demonstrate active functional improvement at the group level. However, based on our clinical experiences, the fact that participation may depend on contextual factors that cannot be modified by treatment.

Acknowledgments
The Botulinum toxin type A was provided by Ipsen.

Table 3. Results

<table>
<thead>
<tr>
<th>Body function and structure</th>
<th>Before BoNT-A</th>
<th>After BoNT-A</th>
<th>P Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAS indicates modified Ashworth scale; MRC, Medical Research Council; #, No. of blocks; ##, No. of metal rods.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elbow flexor MAS</td>
<td>1.5 (1–2)</td>
<td>1 (0–1.25)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Wrist flexor MAS</td>
<td>2 (1–3)</td>
<td>1 (0–2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fingers flexor MAS</td>
<td>1.8 (1–2)</td>
<td>1 (0–1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Thumb flexor MAS</td>
<td>0 (0–1)</td>
<td>0 (0–0)</td>
<td>0.156</td>
</tr>
<tr>
<td>Wrist pronator MAS</td>
<td>1 (0–2)</td>
<td>0 (0–1)</td>
<td>0.002</td>
</tr>
<tr>
<td>Elbow flexor MRC grading</td>
<td>4 (4–4)</td>
<td>4 (3–4)</td>
<td>0.031</td>
</tr>
<tr>
<td>Thumb flexor MRC grading</td>
<td>4 (3–4)</td>
<td>4 (1–4)</td>
<td>0.016</td>
</tr>
<tr>
<td>Maximal grip strength (Jamar dynamometer, Kg)</td>
<td>9.1 ± 6.7</td>
<td>8.2 ± 4.9</td>
<td>0.439</td>
</tr>
<tr>
<td>Maximal key pinch strength (Pinch gauge, Kg)</td>
<td>3.9 ± 2.1</td>
<td>3.6 ± 1.6</td>
<td>0.404</td>
</tr>
<tr>
<td>Manual dexterity (Box and Block test, #)</td>
<td>15.2 ± 10.3</td>
<td>15.3 ± 9.3</td>
<td>0.97</td>
</tr>
<tr>
<td>Digital dexterity (Purdue Pegboard test, ##)</td>
<td>1.4 ± 1.7</td>
<td>1.1 ± 1.6</td>
<td>0.222</td>
</tr>
<tr>
<td>Activity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABILHAND (logit)</td>
<td>0.77 ± 1.37</td>
<td>0.91 ± 1.26</td>
<td>0.492</td>
</tr>
<tr>
<td>Participation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF36</td>
<td>58 (44.5–66.5)</td>
<td>59 (47.5–74)</td>
<td>0.114</td>
</tr>
<tr>
<td>SATIS-Stroke (logit)</td>
<td>1.03 ± 1.03</td>
<td>0.81 ± 1.04</td>
<td>0.101</td>
</tr>
</tbody>
</table>

References

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