Botulinum Toxin and Quality of Life in Patients With Facial Paralysis

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Objectives: To examine the effect botulinum toxin, a potent neurotoxin that causes temporary paralysis of hyperkinetic musculature, has on the quality of life (QOL) in the patient with facial paralysis. We surveyed patients with facial paralysis, using the previously validated Facial Clinimetric Evaluation QOL instrument, before and then again after therapeutic administration of botulinum toxin for the management of their facial hyperkinesis, and performed pair-wise comparisons to determine the effect on patient QOL.

Design: Prospective clinical study at an outpatient facial nerve center.

Results: The overall Facial Clinimetric Evaluation score improved from a mean (SD) of 51.7 (20.9) in the pretreatment group to 63.7 (17.8) in the posttreatment group (P < .05). Statistically significant improvements were noted in all subdomain scores, including Facial Movement, Facial Comfort, Oral Function, Eye Comfort, Lacrimal Control, and Social Function (P < .05 for all comparisons).

Conclusions: Botulinum toxin has a well-established objective benefit in the control of facial hyperkinesis in patients with facial nerve disorders. This study establishes the associated QOL benefit and reaffirms its important role in the multimodality management of patients with facial nerve disorders.

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examine the QOL benefit from botulinum toxin chemodenervation in a selected population of patients with facial nerve disorder, in whom synkinesis and hypertonicity were dominant features.

**METHODS**

Patients were treated in a tertiary care facial nerve center over a 6-month period, from July 2005 through January 2006. Patients were informed as to the nature of the study, and informed consent was obtained for their voluntary enrollment. Sixty-six patients were administered the FaCE questionnaire prior to receiving botulinum toxin chemodenervation therapy and were given a second questionnaire to complete after at least 10 days had passed. The mean age was 48 years (range, 18-82 years; median, 49 years); 49 (74%) were women, and 17 (26%) were men. The study followed institutional guidelines, with institutional review board approval. This allowed the botulinum toxin to take full effect. Survey data were then collected, FaCE scores calculated, and the pretreatment and posttreatment surveys were analyzed for differences using paired t tests, with statistical significance set at P<.05. The FaCE scale domain scores for Facial Movement, Facial Comfort, Oral Function, Eye Comfort, Lacrimal Control, and Social Function were also analyzed for differences. Subjects included in the study were documented to have a clinical response to the botulinum toxin.

**RESULTS**

Of the 66 patients, we obtained complete data from 34 (51.5%) who completed the FaCE survey both before and after botulinum toxin chemodenervation therapy. Of these, 23 (68%) were women and 11 (32%) were men; 44% of these patients were diagnosed with Bell palsy, 15% with Ramsey Hunt syndrome, 6% with dental or orthodontic surgery induced paralysis, 6% with Lyme disease, 6% with acoustic neuromas, and the remaining 23% with meningitis, segmental branch trauma or sacrifice, brain tumors, congenital paralysis, hemifacial spasm, malignant parotid tumors, or idiopathic facial paralysis. The overall FaCE score improved from a mean (SD) of 51.7 (20.9) in the pretreatment group to 63.7 (17.8) in the posttreatment group. Subdomain analysis for Facial Movement, Facial Comfort, Oral Function, Eye Comfort, Lacrimal Control, and Social Function subdomains is detailed in the Table. A statistically significant improvement was noted in all of these subdomains following botulinum toxin therapy (P<.05).

There were no clinical or demographic factors identified that predicted a positive or negative response to botulinum toxin. Analysis of variance analysis failed to demonstrate a statistically significant impact of age, sex, or etiology of facial paralysis on total FaCE scores (P> .05 for all comparisons).

Figure 1. Nasolabial fold asymmetry secondary to left facial hypertonicity.

Figure 2. Examples of synkinesis treated with botulinum toxin. A, Down-turned oral commissure resulting from synkinesis and hypertonicity in the lower face. B, Involuntary platysmal synkinesis.
The benefits of botulinum toxin administration in patients with spasm and hypertonicity are well known. The literature regarding the use of botulinum toxin for facial paralysis has involved isolated clinical cases, small series in which subjective analysis of facial function has been included, and opinion articles.15-28 Although objective improvements in the hypertonicity and synkinesis associated with poorly recovered facial paralysis are obvious to physicians, the impact on patient QOL has not been assessed. It is now widely recognized that QOL, and instruments designed to measure QOL effects of different disease processes and therapies, are equally or perhaps more relevant than objective measures alone.27

In this study, we employed a validated, published QOL survey with respect to facial paralysis and have demonstrated an improvement using that instrument in botulinum toxin–treated patients. Although the sample size is modest, it represents an attempt to quantify the QOL improvement experienced by these patients when properly medically treated. The fact that we demonstrate a statistically significant improvement in mean FaCE scores despite using a survey that was not designed to exclusively examine the relationship of QOL with respect to synkinesis and hypertonicity makes the findings even more relevant (P<.05). Only 3 of 14 questions on the FaCE questionnaire specifically address issues that chemodenervation can improve. By demonstrating a global benefit with this questionnaire, it is possible that a future QOL survey containing a higher number of synkinesis- and hypertonicity-specific questions could demonstrate even more dramatic improvements.

A significant improvement was noted across all subdomains of the FaCE questionnaire, including Facial Movement, Facial Comfort, Oral Function, Eye Comfort, Lacrimal Control, and Social Function (P<.05 for all comparisons). The Table also lists FaCE subdomain scores from a historical cohort of patients with facial paralysis on whom the validation of the FaCE questionnaire was based.14 In our group of patients, the pretreatment FaCE scores are lower than the historical cohort across all subdomains. The administration of botulinum toxin resulted in improvement of all subdomain scores except Facial Comfort to better than the historical cohort. This may indicate the degree of facial discomfort that patients with synkinesis and hyperkinesis experience.

Based on the encouraging findings of this study, our ongoing studies will include the validation of a questionnaire specifically focused on issues associated with synkinesis. Our future endeavors will involve the administration of a synkinesis-specific questionnaire to this patient population, both before and after treatment. The next major advance in the assessment of facial synkinesis will likely be automated, computerized, objective measurements of synkinesis. The present study lays the groundwork for future studies that can correlate the QOL improvements in patients with facial paralysis with objective measures of synkinesis.

Poorly recovered facial paralysis can be a devastating clinical entity. The classic symptoms of synkinesis, hypertonicity, and chronic hemifacial spasm are frequently amenable to judicious botulinum toxin chemodenervation therapy.28 Careful documentation of objective patient facial function, both before and after treatment, are important parameters of the success of this modality. Equally important, however, is the establishment of subjective benefit in terms of QOL.

In the overall management strategy for these patients, which includes minor surgical maneuvers, chemodenervation, and aggressive physical therapy, botulinum toxin chemodenervation of certain hypertonic muscle groups must not be overlooked.

### Table. FaCE Scores, by Subdomain Before and After Botulinum Toxin Therapy

<table>
<thead>
<tr>
<th>Subdomain</th>
<th>Pretreatment</th>
<th>Posttreatment</th>
<th>P Value</th>
<th>Historical Comparison Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial Movement</td>
<td>39.1 (25.7)</td>
<td>49.4 (20.5)</td>
<td>.02</td>
<td>35.1 (29.0)</td>
</tr>
<tr>
<td>Facial Comfort</td>
<td>43.5 (34.5)</td>
<td>57.0 (31.1)</td>
<td>.03</td>
<td>65.0 (27.5)</td>
</tr>
<tr>
<td>Oral Function</td>
<td>62.3 (29.9)</td>
<td>78.3 (22.3)</td>
<td>&lt;.001</td>
<td>65.4 (29.1)</td>
</tr>
<tr>
<td>Eye Comfort</td>
<td>49.4 (34.2)</td>
<td>57.9 (32.0)</td>
<td>.03</td>
<td>57.7 (31.6)</td>
</tr>
<tr>
<td>Lacrimal Control</td>
<td>52.9 (33.6)</td>
<td>66.5 (33.0)</td>
<td>.02</td>
<td>61.1 (36.4)</td>
</tr>
<tr>
<td>Social Function</td>
<td>63.0 (28.9)</td>
<td>74.4 (24.5)</td>
<td>.001</td>
<td>70.1 (26.3)</td>
</tr>
<tr>
<td>Total score</td>
<td>51.7 (20.9)</td>
<td>63.7 (17.8)</td>
<td>&lt;.001</td>
<td>59.3 (19.8)</td>
</tr>
</tbody>
</table>

Abbreviation: FaCE, Facial Clinimetric Evaluation.

* A statistically significant improvement (P<.05) was noted in all subdomain scores and the total score. Data are given as mean (SD).

** Scores from the original FaCE questionnaire validation study.14

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**Figure 3.** Involuntary mentalis puckering (short white arrow) plus ocular and platysmal synkinesis (long white arrow and black arrow).
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Author Contributions: Dr Hadlock had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Hadlock. Acquisition of data: Hadlock. Analysis and interpretation of data: Mehta and Hadlock. Drafting of the manuscript: Mehta and Hadlock. Critical revision of the manuscript for important intellectual content: Hadlock. Statistical analysis: Hadlock. Administrative, technical, and material support: Mehta and Hadlock.

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REFERENCES