

Relationship of Laryngeal Botulinum Toxin Dosage to Patient Age, Vitality, and Socioeconomic Issues

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Summary: Objective. Chemical denervation with botulinum toxin A is the current standard of treatment for spasmodic dysphonia, but dosage is determined individually after a titration period that can take months to years. The objective of this study was to determine if age, body mass index (BMI), overall health, and socioeconomic factors were associated with a patient's optimal dose of botulinum toxin.

Study design and methods. This retrospective chart review looked at 32 patients with stabilized doses of botulinum toxin. Age and BMI were obtained from patient charts, and overall health was assessed by the Short-Form 36 survey.

Results. Analysis showed that BMI was positively correlated with botulinum toxin dose ($r = 0.42$, $P = 0.02$). Overall health showed a positive but nonsignificant association with dose, but subgroup analysis found that adductor spasmodic dysphonia (ADSD) patients without tremor had a significant positive correlation between overall health and dose ($r = 0.50$, $P = 0.04$), whereas tremor-only and mixed dystonia showed a negative nonsignificant correlation. Age was found to have no significant association with dose. Although socioeconomic factors were found to impact the number and frequency of injections, they had no significant impact on the ultimate dosage.

Conclusion. BMI and overall health are positively correlated with higher effective dose and may be useful in guiding clinicians during the titration period.

Key Words: Botulinum toxin–Botox–Botox dosage–Spasmodic dysphonia–ADSD–Vocal tremor–Body mass index.

INTRODUCTION

Laryngeal dystonia is a debilitating and incurable condition marked by breaks in phonation, breathiness, and an overall strained vocal quality.^{1,2} Most commonly, these effects are caused by spasms in the thyroarytenoid (TA) muscle and can occur with or without concurrent vocal tremor.³ This condition is estimated to affect 3 in 100 000 people and disproportionately impacts women.^{2,4,5}

The current standard of treatment is chemical denervation using botulinum toxin serotype A (Botox), and it has been used to treat laryngeal dystonia for more than 25 years.^{3,6} The optimal effective dose—one that maximizes duration of benefit while minimizing adverse effects—varies dramatically among patients.^{2,7} Despite its long history, there also continues to be considerable variation among providers with regard to starting dose and rate of dose titration as an optimal dose is sought.^{6–8} This variation leads to an average of one to five injections to find the optimal dose for a given patient.^{1,2,6,8,9} Given that it takes many years from initial presentation to arrive at the diagnosis of spasmodic dysphonia for most patients, a lengthy dose titration period is simply more time these patients must wait to find relief of their symptoms.¹⁰

As the severity of dystonia is not positively correlated with the amount of botulinum toxin needed to achieve fluency, investigators have sought to identify other patient factors that would have predictive value regarding optimal dose, and recently, they have looked at age and gender as possible indicators with negative results.^{11,12} In an effort to explore other physiological variables that may impact on botulinum toxin dosage, this

study examined the relationship between optimal effective dose and a patient's age, body mass index (BMI), and overall health and vitality. Additionally, socioeconomic factors and their influence on treatment and possible confounding effect on the data were investigated.

METHODS

A retrospective chart review of all patients presenting for botulinum toxin treatment for laryngeal dystonia at our clinic over a 5-month period from December 2011 to April 2012 was conducted. The study design was approved by the institutional review board of the university. All patients with voice complaints completed a questionnaire at every visit that includes, among other indices, the Short-Form (SF-36) survey of overall health and four questions inquiring about what role economic concerns have played in their treatment decisions. The SF-36 survey gives a number of scores, but we focused on the three broadest categories: overall health, physical health, and mental health scores. Patient BMI is also captured at every visit.

We used strict inclusion criteria to minimize confounding factors. We eliminated subjects who presented for abductor spasmodic dysphonia because previous work suggested that botulinum injections were less effective in treating their symptomatology.¹³ We looked only at patients who received botulinum toxin treatment for their dystonia and who received at least five transcutaneous electromyographic (EMG)-guided injections. The three most recent injections had to be the same dosage with at least a patient rating of "good" as recorded in the chart using a seven-point scale: no effects, minimal effects, OK, good, very good, excellent, and perfect. We also excluded patients who received injections in muscles other than the TA muscles. A total of thirty-two patients, 18 adductor spasmodic dysphonia (ADSD) and 14 tremor, were included in the study (Table 1).

The dose of botulinum toxin was calculated in total mouse units (U). For all injections, we calculated the dose as the overall total units of botulinum toxin that the patient received.

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TABLE 1.
Characteristics of Subjects Meeting Inclusion Criteria*

Characteristics	ADSD	Tremor	Total
Number	18 (56)	14 (44)	32
Male	3 (100)	0 (0)	3
Female	15 (52)	14 (48)	29
Mean age (y)	58 ± 13	70 ± 10	63 ± 13
Age range	33–77	50–89	33–89
Unilateral TA injections	5 (38)	8 (62)	13
Bilateral TA injections	13 (68)	6 (32)	19

* Data are mean ± SD or number (%).

The resulting data were analyzed using *GraphPad Prism* version 5.0 for Windows (GraphPad Software, San Diego, CA). Because the data were not normally distributed, all the analyses were nonparametric.

For comparing dose and age, patients were placed in one of two groups: aged less than 50 years or greater than or equal to 50 years. The medians of the two groups were compared using a Mann-Whitney *U* test.

The relationship of BMI with optimal dose was first analyzed using Spearman correlation. Patients were also grouped by whether they were considered overweight according to the BMI scale (≥ 25 kg/m²). The medians of these two groups were compared with a Mann-Whitney *U* test.

Three components of the SF-36 score of general health were used for these analyses: overall health, mental health, and physical health. Spearman correlation was used to evaluate the association of these three scores with botulinum toxin dose. Furthermore, separate correlations were also done comparing the three SF-36 measures and dose among the ASD and tremor patients.

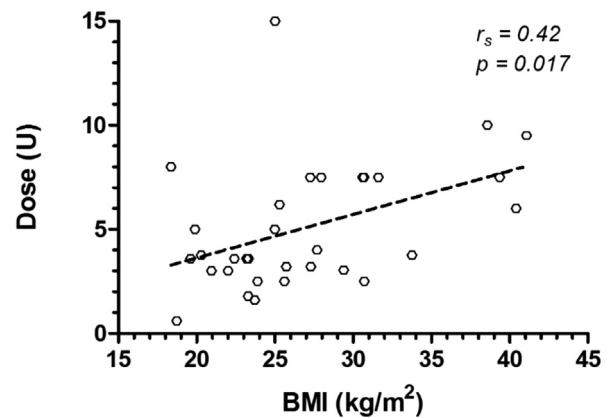
The questionnaire administered to patients contains questions asking about how cost has affected their treatment. Those who reported cost effects were excluded, analyses were performed a second time and the results were compared. Because an overwhelming majority (>95%) of cost concerns were confined to the ASD group, only this group was subjected to the cost analysis.

RESULTS

There was no significant difference in dose between the two age groups ($P = 0.54$). This is consistent with previous reports.¹¹

BMI showed a moderately strong correlation with optimal effective dose ($\rho = 0.42$, $P = 0.02$) (Figure 1). When patients were grouped by BMI as either normal (<25) or overweight/obese (≥ 25), the overweight/obese group had an optimal dose that was nearly double that of the normal group, 6.85 and 3.6 units, respectively ($P = 0.01$) (Figure 2).

Optimal botulinum toxin dose in ASD patients without vocal tremor showed a moderately strong positive correlation with the patient's overall vitality and general health as measured by the SF-36 survey ($\rho = 0.50$, $P = 0.04$) (Figure 3). However, for patients with vocal tremor, the correlation was both negative and not significant ($\rho = -0.30$, $P = 0.3$) (Figure 4). When these groups were combined, these

**FIGURE 1.** Correlation between optimal dose of botulinum toxin and BMI in patients with ASD or tremor dystonia. Trend line added for clarity.

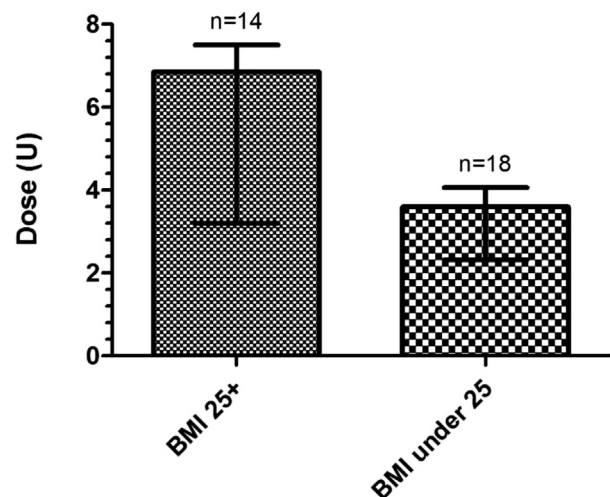
opposing correlations appeared to cancel each other out and be insignificant ($P = 0.23$) (Figure 5).

There was no significant difference in effective dose between patients who said cost had impacted their treatment and those who said costs did not impact their treatment ($P = 0.89$). However, institutional billing data showed that the number of injections administered in our practice has measurably declined since the coding changes that occurred in 2010, which in resulted in greater out-of-pocket cost per visit.

DISCUSSION

BMI showed significant positive correlation overall with patients' ultimate stabilized dose of botulinum toxin, and SF-36 score of overall health showed a positive dose correlation in the ASD subset of patients. In the tremor subgroup, SF-36 demonstrated a negative, nonsignificant correlation with dose. Neither age nor socioeconomic factors appeared to have any significant impact.

The reasoning behind these correlations is speculative at this point but may stem from a number of factors. One likely factor

**FIGURE 2.** All subjects were grouped by BMI and the median doses compared. Error bars show interquartile range. $P = 0.012$.

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