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OUTCOMES OF BOTULINUM TOXIN TYPE A IN THE TREATMENT OF ESSENTIAL BLEPHAROSPASM AND HEMIFACIAL SPASM: AN ORIGINAL STUDY

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Abstract

Background: Facial dystonias, including essential blepharospasm and hemifacial spasm, are disabling movement disorders characterized by involuntary contractions of periocular and facial muscles. Botulinum toxin type A (BtA) is considered the first-line therapy; however, treatment response and duration vary depending on underlying etiology and dosing strategy. **Objective:** To evaluate the clinical outcomes of a regional preparation of BtA in patients with essential blepharospasm and hemifacial spasm and to identify factors associated with prolonged symptom-free intervals. **Methods:** This retrospective observational study included patients with primary or secondary facial dystonias who received at least one injection of BtA between May 2022 and April 2024 at a tertiary eye care center. Disease severity was assessed using the Jankovic Rating Scale (JRS) for blepharospasm and the Samsung Medical Center (SMC) grading system for hemifacial spasm. Outcomes assessed included change in severity score, symptom-free interval, complications, and correlation of dose with duration of effect. Statistical analysis included Student's t-test, chi-square test, one-way ANOVA, and Spearman's correlation. **Results:** Twenty-six patients (76 treatment sittings) were analyzed. The mean age was 56.62 ± 10.56 years. Significant improvement in severity was observed one-week post-injection. The overall mean symptom-free interval was 139.92 ± 58.53 days. Primary dystonias demonstrated significantly longer symptom-free intervals than secondary dystonias ($p = 0.02$). Dose escalation significantly prolonged the duration of relief ($p = 0.004$) without increasing complication rates. Lagophthalmos was the most common complication and resolved conservatively. **Conclusion:** BtA is a safe and effective treatment for facial dystonias. Primary dystonias respond more favorably. Individualized dose escalation improves therapeutic duration without increasing adverse events.

Keywords: *botulinum toxin type A, essential blepharospasm, hemifacial spasm, facial dystonia, chemodenervation*

Introduction

Facial dystonias are focal hyperkinetic movement disorders characterized by involuntary, repetitive contractions of muscles innervated by the facial nerve. The two most common clinical entities are essential blepharospasm and hemifacial spasm. Essential blepharospasm is a bilateral periocular dystonia that may progress to sustained eyelid closure and functional blindness in severe cases [1]. Hemifacial spasm, in contrast, typically presents as unilateral tonic or clonic facial contractions and is most frequently associated with vascular compression at the facial nerve root exit zone [2,3].

Epidemiological studies demonstrate a higher prevalence among middle-aged and elderly individuals, with female predominance [4,5]. Although not fatal, these disorders significantly impair quality of life, contributing to visual disability, psychosocial stress, and occupational limitation [6]. Objective evaluation of severity is critical for monitoring treatment response. The Jankovic Rating Scale (JRS) has been validated as a reliable clinical outcome tool, showing strong correlation between severity and frequency components in blepharospasm assessment [7]. Management strategies include conservative measures, systemic pharmacotherapy, surgical intervention, and chemodenervation. Non-pharmacological approaches such as tinted lenses and sensory tricks offer temporary benefit [8]. Oral agents, including benzodiazepines and dopaminergic drugs, frequently provide suboptimal relief and are associated with cognitive and sedative side effects [8]. Microvascular decompression offers definitive management for compressive hemifacial spasm but carries procedural risks including facial weakness and cerebrovascular complications [2,9]. Interestingly, prior botulinum toxin exposure has been shown to influence intraoperative monitoring parameters such as lateral spread response during decompression procedures [3,10].

Botulinum toxin type A (BtA) has emerged as the gold standard therapy for focal facial dystonias. By inhibiting acetylcholine release at the neuromuscular junction, BtA produces reversible chemodenervation and symptomatic improvement [11]. Randomized trials and long-term observational studies have demonstrated its efficacy and safety in essential blepharospasm and hemifacial spasm, with sustained benefit across repeated injection cycles [12-14]. Predictors of therapeutic response and duration, however, remain variable. Some studies suggest that disease subtype, baseline severity, and cumulative exposure may influence outcomes [15]. Additionally, methodological rigor in retrospective outcome studies is essential to ensure accurate interpretation of real-world clinical data [16].

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Despite extensive clinical use, gaps remain regarding optimal dosing strategies, response differences between primary and secondary dystonias, and factors associated with prolonged symptom-free intervals. The present study was undertaken to evaluate the outcomes of a regional preparation of botulinum toxin type A in essential blepharospasm and hemifacial spasm and to identify predictors of extended therapeutic response.

Materials and Methods

This retrospective observational study was conducted at a tertiary eye care center over a two-year period from May 2022 to April 2024. Institutional review board approval was obtained prior to commencement of the study. The research adhered to the tenets of the Declaration of Helsinki. As the study involved retrospective analysis of existing medical records without direct patient interaction, the requirement for informed consent was waived.

Study Population

Medical records of patients diagnosed with essential blepharospasm or hemifacial spasm who received at least one injection of botulinum toxin type A (BtA) during the study period were reviewed. Patients were included if they had a confirmed clinical diagnosis of either primary or secondary facial dystonia and had complete documentation of pre- and post-injection clinical assessments. Records with incomplete data, patients lost to follow-up before the first post-injection evaluation, or cases where alternative movement disorders were suspected were excluded from analysis.

Pre-Injection Clinical Evaluation

All patients underwent a comprehensive evaluation prior to administration of BtA. A detailed medical and psychiatric history was obtained to exclude functional or psychogenic movement disorders. Drug history was carefully reviewed to rule out acute or tardive dyskinesia associated with dopamine receptor-blocking agents. Each patient underwent a complete ophthalmic examination, including slit-lamp biomicroscopy, to exclude secondary causes of blepharospasm such as blepharitis, trichiasis, entropion, corneal epithelial defects, foreign bodies, ocular surface inflammation, or intraocular inflammation. A thorough neurological examination, including cranial nerve assessment, was performed in all cases to identify secondary dystonia. In patients with hemifacial spasm, magnetic resonance imaging (MRI) of the brain was performed to evaluate for vascular compression or other structural pathology affecting the facial nerve.

Severity Assessment

The severity of essential blepharospasm was graded using the Jankovic Rating Scale (JRS), which consists of two components: a severity score and a frequency score, each graded from 0 to 4. The final severity grade was calculated as the sum of these two components, yielding a total score ranging from 0 to 8. Hemifacial spasm was graded using the Samsung Medical Center (SMC) grading system, a four-point scale that categorizes disease severity based on the extent of facial involvement and functional impairment. Pre-injection and post-injection severity grades were documented for all patients.

Injection Technique

All injections were administered by a single experienced surgeon to ensure procedural consistency. A commercially available preparation of botulinum toxin type A (XEOMIN®, 50 IU vial) was reconstituted with 2 mL of sterile, pyrogen-free normal saline to achieve a concentration of 2.5 IU per 0.1 mL. In cases of essential blepharospasm, injections were administered into the medial and lateral pretarsal orbicularis oculi of both upper and lower eyelids. The procerus and corrugator supercilii muscles were injected selectively depending on clinical involvement. In hemifacial spasm, injections were delivered at eight to ten sites based on the distribution and severity of muscle involvement. Each injection site received 2.5 to 5 IU of BtA. The total dose per sitting ranged from 20 IU to 50 IU and was individualized based on baseline severity, prior therapeutic response, and suspected resistance. In selected cases demonstrating suboptimal response or increased symptom severity, dose escalation was performed during subsequent sittings.

Follow-Up and Outcome Measures

Patients were evaluated seven days after injection to assess therapeutic response and detect early complications. The primary outcome measures included reduction in severity score and the duration of the symptom-free interval, defined as the time in days between injection and recurrence of clinically significant dystonic symptoms necessitating reinjection. Secondary outcome measures included the occurrence of adverse effects such as lagophthalmos, ptosis, ectropion, corneal punctate erosions, facial asymmetry, and deviation of the angle of the mouth. In patients reporting symptoms suggestive of dry eye, Schirmer's test was performed to assess tear production.

Statistical Analysis

All data were compiled and analyzed using standard statistical software. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Comparative analyses were conducted using Student's t-test for continuous variables and chi-square test for categorical variables. One-way analysis of variance (ANOVA) was used to compare mean differences among multiple groups. The correlation between total dose administered and duration of symptom-free interval was assessed using Spearman's rank correlation coefficient. A p-value of less than 0.05 was considered statistically significant.

Results

Demographic and Clinical Characteristics: A total of 26 patients met the inclusion criteria during the study period. These patients collectively underwent 76 sittings of botulinum toxin type A (BtA) therapy. The mean age at presentation was 56.62 ± 10.56 years. The mean duration of follow-up was 1.86 ± 2.06 years. Among the study population, three patients (11.5%) were diagnosed with essential blepharospasm and 23 patients (88.5%) had hemifacial spasm. Seven patients (26.9%) demonstrated radiological evidence of vascular loop syndrome on magnetic resonance imaging. No medical records were excluded due to incomplete documentation. [Table 1]

Table 1: Demographic and Clinical Profile of Study Participants

Variable	Value
Total patients	26
Total injection sittings	76
Mean age (years)	56.62 ± 10.56
Mean follow-up duration (years)	1.86 ± 2.06
Essential blepharospasm	3 (11.5%)
Hemifacial spasm	23 (88.5%)
Vascular loop syndrome	7 (26.9%)

Reduction in Disease Severity: Significant clinical improvement was observed at the first follow-up visit, conducted seven days after injection. In patients with essential blepharospasm, the modal Jankovic Rating Scale (JRS) score reduced from 5 prior to injection to 0 post-injection. In patients with hemifacial spasm, the modal Samsung Medical Center (SMC) grade reduced from 2 to 0 after treatment. These findings indicate marked early symptomatic relief following BtA administration across both primary and secondary facial dystonias.

Symptom-Free Interval and Dose Distribution: The overall mean symptom-free interval across all sittings was 139.92 ± 58.53 days. The majority of sittings involved a total dose of 25 IU (n = 51; 67.1%). The mean symptom-free intervals corresponding to different dose categories

are summarized below.

Table 2: Mean Symptom-Free Interval According to Total Dose

Total Dose (IU)	No. of Sittings	Percentage (%)	Mean Interval (days)	SD
20	6	7.9%	102.1	44.7
22.5	7	9.2%	132.4	35.3
25	51	67.1%	147.2	61.6
30	8	10.5%	124.4	55.1
50	4	5.3%	142.4	59.7
Total	**76**	**100%**	–	–

Spearman's rank correlation analysis demonstrated no statistically significant correlation between total dose administered in a sitting and the duration of the symptom-free interval ($\rho = 0.12$; $p = 0.31$). However, a statistically significant increase in the symptom-free interval was observed with a higher number of treatment sittings ($F = 3.87$; $p = 0.026$), suggesting possible cumulative benefit with repeated injections.

Primary Versus Secondary Dystonia: When comparing primary and secondary dystonias, primary dystonias were associated with significantly longer disease-free intervals. The mean symptom-free interval for primary dystonias was 135.11 ± 54.15 days, whereas secondary dystonias demonstrated a mean interval of 75.29 ± 48.89 days. This difference was statistically significant on one-way ANOVA analysis ($F = 6.46$; $p = 0.02$). [Table 3]

Table 3: Comparison of Symptom-Free Interval Between Primary and Secondary Dystonia

Dystonia Type	Mean Interval (days)	Standard Deviation	p-value
Primary	135.11	54.15	0.02
Secondary	75.29	48.89	

Effect of Dose Escalation: In nine sittings, the total dose of BtA was increased due to increased severity of symptoms or presumed resistance to prior treatment. Dose escalation resulted in a statistically significant prolongation of the symptom-free interval ($F = 15.49$; $p = 0.004$). The mean duration of relief increased from 98.4 days prior to escalation to 156.2 days following dose increment. Importantly, there was no statistically significant increase in overall complication rates following dose escalation ($p = 0.48$).

Table 4: Effect of Dose Escalation on Symptom-Free Interval

Parameter	Before Escalation	After Escalation	p-value
Mean interval (days)	98.4	156.2	0.004
Complication rate	Comparable	Comparable	0.48

Complication Profile: The overall complication profile was mild and self-limiting. The most frequently observed complication was lagophthalmos, occurring in 26.3% of sittings (n = 20). Other complications included ptosis and deviation of the angle of the mouth. All cases of lagophthalmos were managed conservatively with lubricating eye drops and nighttime lid taping. Symptoms resolved spontaneously within three to five weeks. No systemic, vision-threatening, or life-threatening complications were reported. The complication rate did not differ significantly between primary (33.3%) and secondary dystonia (42.9%) groups.

Table 5: Distribution of Complications

Complication	Frequency (%)
Lagophthalmos	26.3
Ptosis	3.9
Angle of mouth deviation	3.9
Corneal erosions	0
Systemic complications	0

Discussion

The present study evaluated the clinical outcomes of botulinum toxin type A (BtA) in patients with essential blepharospasm and hemifacial spasm and examined factors influencing the duration of symptom-free intervals. Our findings confirm that BtA provides significant symptomatic improvement with a favorable safety profile, consistent with established evidence supporting its role as first-line therapy for focal facial dystonias.

A marked reduction in severity scores was observed within one week of injection in both blepharospasm and hemifacial spasm. This rapid onset of action aligns with the known pharmacodynamics of BtA, which acts by inhibiting acetylcholine release at the neuromuscular junction, producing reversible chemodenervation [11]. Previous randomized controlled trials and observational studies have similarly demonstrated substantial improvement in dystonic contractions within days of administration [12-14].

The mean symptom-free interval in our cohort was approximately 140 days, which is comparable to long-term outcome data reported by Czyz et al., who observed sustained benefit with repeated injections over extended follow-up periods [3]. Similarly, long-term safety and efficacy analyses by Koller et al. have shown that repeated BtA administration remains effective without cumulative toxicity [15]. These findings reinforce the durability and safety of repeated chemodenervation cycles.

An important observation in our study was the significantly longer symptom-free interval in primary dystonias compared to secondary dystonias. Essential blepharospasm is generally considered a primary basal ganglia circuit disorder [8], whereas hemifacial spasm often results from mechanical vascular compression of the facial nerve [2,9]. Persistent structural irritation in secondary dystonias may limit the duration of therapeutic benefit following chemodenervation. This difference underscores the importance of etiological classification when counseling patients regarding expected treatment duration.

Although total dose did not demonstrate a statistically significant overall correlation with duration of effect, dose escalation in selected cases resulted in significant prolongation of symptom-free intervals without increasing complication rates. This supports an individualized dosing approach rather than rigid fixed-dose protocols. Prior studies have suggested that baseline severity and disease characteristics may influence response to therapy [13,15], and our findings are consistent with this tailored treatment strategy.

The complication profile observed in this study was mild and self-limiting. Lagophthalmos was the most common adverse event, resolving with conservative management. These results are consistent with previously reported safety data, which indicate that periocular injections are generally well tolerated and associated with transient, localized side effects [12,14,15]. Importantly, no systemic or vision-threatening complications were observed.

In contrast to microvascular decompression, which offers definitive treatment in selected cases but carries procedural risks [2,9], BtA remains a minimally invasive and safe alternative. Furthermore, prior botulinum toxin exposure has been shown to influence intraoperative monitoring parameters during decompression surgery [3,10], highlighting the complex interplay between chemodenervation and surgical management.

The strengths of this study include standardized injection technique by a single surgeon, objective severity grading using validated scales, and analysis of dose-adjustment strategies. However, limitations include its retrospective design, relatively small sample size, and absence of patient-reported quality-of-life measures. Additionally, variability in dosing intervals inherent to real-world practice may introduce confounding factors. Overall, this study reinforces the efficacy and safety of botulinum toxin type A in the management of facial dystonias and suggests that primary dystonias and individualized dose escalation strategies are associated with prolonged therapeutic benefit. Prospective studies with larger cohorts and standardized outcome measures are warranted to further refine predictive models of response.

Conclusion

Botulinum toxin type A is an effective and well-tolerated treatment for essential blepharospasm and hemifacial spasm. In this study, patients experienced significant reduction in symptom severity within one week of injection, with a mean symptom-free interval of approximately four to five months. Primary dystonias demonstrated longer disease-free intervals compared to secondary forms. Individualized dose escalation in selected cases prolonged therapeutic benefit without increasing adverse events. The overall complication profile was mild and self-limiting. These findings support the continued use of botulinum toxin as first-line therapy and highlight the importance of tailored dosing strategies to optimize clinical outcomes.

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