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Effects of Botulinum Toxin Type A Injection in Patients with Bruxism and Masseter Muscle Hypertrophy

Bruksizm ve Masseter Kas Hipertrofisi Olan Hastalarda Botulinum Toksin Tip A Enjeksiyonunun Etkileri

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ABSTRACT

Objective: The aim of this study was to evaluate the efficacy of botulinum toxin type A injection on the severity and incidents of bruxism and joint noise and for pain in patients during the management of bruxism and masseter muscle hypertrophy.

Methods: Sixteen adults who had bruxism and bilateral masseter muscle hypertrophy were included in this study. One-session 30 U botulinum toxin type A injection was performed. Maximum interincisal mouth opening, visual analog scale evaluations, and severity and incident of bruxism were recorded at 3 times: baseline and 1 month and 8 months after the injection. Patient satisfaction was assessed only at 8 months after the injection.

Results: Significant decreases were observed in pain complaints, restriction in mouth opening, and severity of bruxism at 1 month and 8 months. Bite force decreased significantly at 1 month, but it returned to baseline levels at 8 months. Self-perceived pathologic sound decreased significantly at 8 months. No significant change was observed in painless maximum interincisal mouth opening and mastication efficiency at 1 month and 8 months. Patient satisfaction was good at 8 months.

Conclusion: Botulinum toxin type A injection lessened severity and incidents of bruxism and reduced joint noise and pain in patients with bruxism and masseter muscle hypertrophy, and botulinum toxin type A injection produced greater patient satisfaction.

Keywords: Botulinum toxin Type A, bruxism, masseter muscle hypertrophy

ÖZ

Amaç: Bu çalışmanın amacı; bruksizm ve masseter kas hipertrofisi tedavisi gören hastalarda Botulinum Toksin Tip A enjeksiyonunun bruksizm şiddeti ve sıklığı ile eklem ağrısı ve sesi üzerindeki etkinliğinin incelenmesidir.

Yöntemler: Bu çalışma bruksizm ve çift taraflı masseter kas hipertrofisi olan 16 erişkin hastayı içermektedir. Hastalara 30 U Botulinum Toksin Tip A enjeksiyonu yapılmıştır. Maksimum ağız açıklığı miktarı, görsel analog skala incelemeleri ile bruksizm şiddeti ve sıklığı 3 farklı zamanda kayıt edilmiştir: Tedavi başında, enjeksiyondan 1 ay sonra ve enjeksiyondan 8 ay sonra. Hasta memnuniyeti ise sadece enjeksiyondan 8 ay sonra değerlendirilmiştir.

Bulgular: Ağrı şikâyetleri, ağız açmadaki kısıtlılık ve bruksizmin şiddetinde tedavinin 1. ve 8. aylarında önemli azalmalar gözlemlenmiştir. Isırma kuvveti tedavinin 1. ayında önemli şekilde azalmış fakat tedavinin 8 ayında tedavi başlangıcındaki seviyelere geri dönmüştür. Bireysel olarak algılanan patolojik eklem sesi tedavinin 8. ayında önemli şekilde azalmıştır. Ağrısız maksimum ağız açıklığı ve çiğneme etkinliğinde tedavinin 1. ve 8. aylarında önemli değişimler gözlemlenmemiştir. Tedavinin 8. ayındaki hasta memnuniyet seviyesinin iyi olduğu görülmüştür.

Sonuç: Bruksizm ve masseter kas hipertrofisi olan hastalarda; Botulinum Toksin Tip A enjeksiyonu bruksizm şiddeti ve sıklığı ile eklem ağrısı ve sesini azalmıştır ve Botulinum Toksin Tip A enjeksiyonu yüksek oranda hasta memnuniyeti oluşturmuştur.

Anahtar Kelimeler: Botulinum toksin tip A, bruksizm, masseter kas hipertrofisi

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INTRODUCTION

Bruxism is a serious and uncomfortable condition, and it unfortunately is seen commonly in the Turkish population. Bruxism is defined as an unwanted oral habit consisting of involuntary clenching, bracing, grinding, or gnashing of teeth.[1]

Bruxism can show profound clinical signs and symptoms: masseter and temporalis muscle hypertrophy, myositis, morning jaw stiffness, and tooth sensitivity. Patients with bruxism are prone to experience jaw pain and limitation of jaw movement, which occur 3-4 times greater than in subjects with no bruxism.[1]

Unilateral or bilateral enlargement of masseter muscles is known as masseter muscle hypertrophy (MH). Muscle hypertrophy is characterized by a soft tissue enlargement near the angle of the mandible. The soft tissue enlargement may be associated with facial pain and can be obvious and cosmetically disfiguring.[2]

Muscle hypertrophy occurs more frequently in 20- to 40-year-old adults, with no gender distinction. The etiology of MH in children or adults may be multifactorial, and the exact etiology is uncertain.[3]

Several treatment modalities have been advocated for the management of MH: use of radiofrequency, botulinum toxin injections, a number of surgical methods such as partial resection of the masseter muscle and modeling osteotomy in the region of the masseteric tuberosity, conservative therapeutic approaches such as use of occlusal splints for the prevention of parafunctional habits, and systemic administration of muscle relaxants.[2]

Botulinum toxin is a powerful neurotoxin and produced by the gram-positive anaerobic organism *Clostridium botulinum*. It reversibly blocks presynaptic acetylcholine release at the neuromuscular junction.[3] Van Zandijcke and Marchau[4] first described botulinum toxin injection for patients with bruxism, and this injection method has gained popularity among clinicians.

Botulinum toxin type A (BTX-A) injection has been advocated for the management of orofacial muscle spasm or hypertrophies and bruxism[5-9] as well as for treatment of MH.[10] For patients with severe bruxism, some authors advocated the injection of botulinum toxin in both masseter and temporal muscles,[4,11,12] whereas others[13] suggested only masseter muscle injection to reduce bruxism.

However, the possible effectiveness of a reversible paralytic agent like BTX-A injection for treating bruxism and masseter muscle hypertrophy has been neglected in the literature. Thus, this study aimed to evaluate the efficacy of BTX-A injection on severity and incidents of bruxism and joint noise and pain in patients with bruxism and masseter muscle hypertrophy.

METHODS

The author designed a prospective clinical study composed of patients with bruxism and disfiguring MH who underwent 1-session bilateral BTX-A injection treatment.

This study was approved by the ethics committee (approval number: 2014/12). Patients were informed about the study design and potential side effects of BTX-A. All participants signed an informed consent agreement. The author confirms to have read the Helsinki Declaration and to have followed the guidelines for this investigation.

The following criteria were used to include patients in the study sample: (1) MH diagnosed through clinical self-evaluation (the soft tissue enlargement at near the angle of the mandible may be prominent enough to be considered cosmetically disfiguring) and magnetic resonance imaging (MRI) evaluations including patients with bilateral masseter hypertrophy, characterized by a soft enlargement that was associated with facial and masseter pain near the angle of the mandible; (2) incidents of bruxism; (3) age >16 years; (4) no underlying pathology diagnosed by MRI; (5) adequate existing clinical data at baseline (T0) and 1 month (T1) and 8 months (T8) after the injections.

Patients were excluded if they had pregnancy, drug allergy history, systemic disorders, inflammatory or malignant disease, previous temporomandibular joint treatment, and any individuals who had inadequate existing data at T0 and T1 and T8 after the injections.

The sample size was calculated with power analysis. A significance level of .05 and a test power of 80% was considered to detect a clinically meaningful difference of 4 mm in maximum interincisal mouth opening (MIO).[13] The power analysis showed that 11 patients were required for this study.

BTX-A Injection

The BTX-A (Botox, Allergan, İstanbul, Turkey) was supplied as a freeze-dried powder. The BTX-A was reconstituted gently with 1 mL of sterile saline solution, giving a concentration of 10 U/0.1 mL. The constituted drug was used immediately. Thirty units BTX-A was injected per side. The injection was carried out by using a 1 mL insulin syringe with a 26G, 0.5 inch needle. The toxin was injected equally into 2 regions (1 cm apart from each other) at the center of lower third of masseter muscle that were located each other after the disinfection as advocated by Lee et al.[14] Disinfection of the region was done by povidone–iodine solution. After the application, contamination with water was prohibited at the injection site for a few hours.

Clinical Parameters

Painless MIOs, visual analog scale (VAS) evaluations (mastication efficiency, pain complaints, self-perceived sounds and bite force, and restriction at mouth opening), and severity and incidents of bruxism and patient satisfaction were obtained.

A scale including 5 grading levels (0 = absent; 1 = slight; 2 = moderate; 3 = intense; and 4 = severe) was used to assess the severity of bruxism. Another scale including 5 grading levels (1 = no satisfaction; 2 = less; 3 = moderate; 4 = good; and 5 = excellent) was used to assess patient satisfaction. The patient marked 1 of the 5 levels accordingly on the line, and the marked level is assigned as the score of patient satisfaction or severity of the bruxism.

All assessments were recorded at baseline (T0) and 1 month (T1) and 8 months (T2) after the injection. The author performed all the evaluations.

Statistical Analysis

All statistical analyses were carried out using the Statistical Package for Social Sciences, version 17.0 software (SPSS Inc.; Chicago, IL, USA). Comparisons of time points (T0, T1, and T2) of parametric data (MIO and VAS evaluations) were done with repeated measures of analysis of variance (Tukey test). Comparisons of time points of severity of bruxism were done with Wilcoxon signed-rank test. Statistical significance was set at $P < .05$.

RESULTS

The sample was composed of 16 subjects (14 female and 2 male) with bruxism and bilateral MH. The mean age was 27.88 ± 9.32 years, and the mean follow-up period after the injection was 8.00 ± 2.13 months.

Table 1. Descriptive Data for Outcome Variables at Baseline and 1 Month and 8 Months After Treatment

Outcome Variables	Baseline (T0)	One Month (T1)	Eight Months (T2)
Pain complaints (VAS score)	5.34 ± 3.08	3.36 ± 3.21	1.84 ± 2.30
Mastication efficiency (VAS score)	8.30 ± 2.03	7.75 ± 1.61	8.63 ± 2.02
Bite force (VAS score)	9.53 ± 1.36	6.85 ± 2.61	9.11 ± 2.15
Self-perceived sound (VAS score)	7.53 ± 2.98	5.76 ± 3.88	1.39 ± 1.63
Painless MIO (mm)	34.31 ± 13.28	35.21 ±7.83	36.63 ± 6.72
Restriction at mouth opening (VAS score)	3.99 ± 3.57	0.87 ± 2.69	0.73 ± 2.48
Severity of bruxism (5 grading levels)	3.13 ± 1.26	1.29 ± 0.99	1.19 ± 1.17

MIO, maximum interincisal openings; VAS, visual analog scale.

The mean follow-up period after the treatment was calculated as 8.00 ± 2.13 months. Descriptive data for outcome variables at T0, T1, and T2 are shown in Table 1.

Statistical analysis showed that pain complaints, restriction of mouth opening, and severity of bruxism decreased significantly 1 month after the BTX-A injection, and these improvements remained relatively stable during the 8-month follow-up period. Bite force decreased at a statistically significant level 1 month after BTX-A injection, but it returned to baseline levels after 8-month follow-up period. Self-perceived sound showed insignificant decrease 1 month after the BTX-A injection, but this decrease reached a statistically significant level during the follow-up period. No statistically significant change was observed in painless MIO and mastication efficiency after the injection or during the follow-up period (Table 2).

About 81.3% of patients were reported to have high pleasure scores (high satisfaction) at T2. The mean of patient satisfaction was 4 (good) at T2 (Table 3).

Pain around the injection site in the first 1 month after the BTX-A injection was seen in 2 patients, though the side effects were found to be transitory.

DISCUSSION

The study sample comprised patients who had symptoms of bruxism and bilateral MH. Computed tomographic, MRI, ultrasonographic, and electromyographic measurements have been used in diagnosis of MH, in addition to clinical findings.[2,5,7] In the present study, MH was diagnosed with clinical and MRI evaluations, characterized by a soft enlargement that was associated with facial and masseter pain near the angle of the mandible.

Onabotulinumtoxin A (BTX-A or Botox) was used as a botulinum toxin injection agent in the present study. It has been well documented that BTX-A produced significant improvements in MH and cosmetic appearance of the subjects with reduction of muscle volume[9,10] and decreased electromyographic activity of the muscle.[7]

Table 2. Results of Repeated Measures Analysis of Variance Test Explaining the Significances in Variance Analyses

Outcome Variable	Comparisons (T1-T0)	(T2-T0)	(T2-T1)	Test
Pain complaints (VAS score)	$P < .05$	$P < .01$	$P > .05$	†
Mastication efficiency (VAS score)	$P > .05$	$P > .05$	$P > .05$	†
Bite force (VAS score)	$P < .01$	$P > .05$	$P < .05$	†
Self-perceived sound (VAS score)	$P > .05$	$P < .001$	$P < .01$	†
Painless MIO (mm)	$P > .05$	$P > .05$	$P > .05$	†
Restriction of mouth opening (VAS score)	$P < .01$	$P < .01$	$P > .05$	†
Severity of bruxism (5 grading levels)	$P < .01$	$P < .01$	$P > .05$	‡

MIO, maximum interincisal mouth opening; T0, baseline; T1, 1 month after BTX-A injection; T21, 8 months after BTX-A injection; VAS, visual analog scale.
† Repeated measures test (Tukey test). ‡ Wilcoxon signed-rank test.

Table 3. Patient Satisfaction Rates (%)

Satisfaction Degrees	%
No satisfaction	6.3
Low satisfaction	0.0
Moderate satisfaction	12.5
Good satisfaction	50.0
Excellent satisfaction	31.2
Total	100

To achieve maximum dose response and to minimize side effects of the injection, clinicians should use the most effective dose at the smallest volume. We used a 30 U BTX-A dose for one side. Many authors[4,14] suggest that an adequate dose of BTX-A should be >20 U for long-term effectiveness up to 9 months. Other researchers[2,15] injected 30 U Botox in the hypertrophic masseter muscle and found favorable patient satisfaction during 10 months of follow-up.

The results of the present study showed that pain complaints and restriction of mouth opening decreased significantly 1 month after BTX-A injection, and these improvements remained relatively stable during the 8-month follow-up period. Bite force decreased reaching a statistically significant level 1 month after the BTX-A injection, but it returned to baseline levels after the 8-month follow-up period. Self-perceived sound showed insignificant decrease 1 month after BTX-A injection, but this decrease reached a statistically significant level during the follow-up period. No statistically significant change was observed in painless MIO and mastication efficiency after the injection or during the follow-up period.

Guarda-Nardini et al[12] carried out a study on 20 patients with bruxism. They evaluated the effects of masseter and temporal muscle BTX-A injections on mastication efficiency, pain complaints during chewing and rest, and MIO of the patients with sleep bruxism at baseline and 1 week, 1 month, and 6 months after the injections. When considering the BTX-A group in the study of Guarda-Nardini et al,[12] mean changes in mastication efficiency and MIO were similar with those observed in this study. Guarda-Nardini et al[12] reported that mastication efficiency was 7.70, 7.10, 6.40, and 7.40 VAS scores at baseline and after 1 week, 1 month, and 6 months after the injections, respectively. They also reported an approximately 2 mm increase in MIO at 6 months after the injections.

However, Guarda-Nardini et al[12] reported approximately 1.5 VAS score decrease in pain complaints in the BTX-A group, but we observed a 3.5 VAS score decrease in this parameter. These conflicting results can result from differences in the pain complaint evaluation method, the number of BTX-A-injected muscles (i.e., masseter and temporal muscles), and observation periods (i.e., shorter observation period) between the 2 studies.

Song et al[15] studied the pattern of mastication and force distribution after BTX-A injection into masseter muscles. They injected a total of 25 U BTX-A (50 U in total). The results of this study indicated significant change in force balance between 2 sides over time.

The findings of the present study also showed that severity of bruxism decreased significantly 1 month after BTX-A injection, and it remained relatively stable during the 8-month follow-up period. Supporting the results of this study,recent studies[7,14] have reported decreased subjective bruxism symptoms and bruxism events after 3 months of masseter BTX-A injection.

In the present study, 81.3 % of the patients reported high pleasure scores after the follow-up period. Redaelli[16] used BTX-A injection in the masseter muscle for the treatment of bruxism and found that 65.8% and 4.2% of the patients reported good and excellent improvements in the symptoms of bruxism, respectively.

Recent literature reviews[17] suggest that botulinum toxin injections are effective for preventing bruxism and that botulinum toxin is safe to use at a dosage of <100 U for otherwise healthy patients.

Actually, BTX is a powerful neurotoxin. The toxin injected into the muscle binds to the motor nerve (cholinergic terminal), gets absorbed into the cytoplasm of the terminal, and reversibly blocks the release of presynaptic acetylcholine at the neuromuscular junction. Thus, injection of botulinum toxin into the muscle causes masseter paralysis.[18] It acts selectively at the peripheral cholinergic nerve endings to produce muscle relaxation, diminished compression of the muscle vessels, and occasionally a reduction in the concentration of excitatory neuropeptides.[3,19] Patients tend to use paralyzed masseter muscles without full function and with reduced action. Possibly, reduced bruxing events in the masseter muscle depend on both decreased action potentials and muscle atrophy as time passes.

Study Limitations

Despite the fact that the results of this study showed favorable clinical outcomes after the BTX-A injection, the results must be interpreted with caution due to its limitations. First, this study had subjective evaluations (i.e., VAS score and 5-level grading evaluations). Second, the sample size of this study limits the generalizability of the findings.

CONCLUSION

Within the limitations of the present study, the findings of this study suggest that BTX-A injection lessened the severity and incidents of bruxism and reduced joint noise and pain in patients with bruxism and masseter muscle hypertrophy, and BTX-A injection produced greater patient satisfaction.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Faculty of Dentistry, Atatürk University, (Date: 2014, Number: 12).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

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