

Research Article

## Effectiveness of Onabotulinum Toxin-A in Treatment of Sleep Bruxism

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### Abstract

**Introduction:** *Bruxism is a movement disorder characterized by excessive teeth grinding or jaw clenching. Several treatment modalities i.e. devices (dental guards and occlusal splints), psychosocial interventions and pharmacotherapies have been tried; but they are ineffective in the majority of patients. Recently botulinum toxin (BTX) has been used and found useful in the treatment of bruxism. This study was done to evaluate the effectiveness of botulinum toxin A in the treatment of symptomatic sleep bruxism (SB).*

**Methodology:** *Patients with a history of disabling sleep bruxism refractory to medical or dental treatment were administered botulinum toxin injection after obtaining written informed consent. In all patients, a dose of 20 mouse units (MU) of BTX-A was injected into the right and left masseters at four sites.*



**Results:** *There were seven patients with refractory bruxism included in the study (4 male and 3 female), aged 5–52 (mean age  $20.57 \pm 15.91$ ) and mean duration of symptoms  $4.71 \pm 2.81$  years (range 2–9 years). All patients reported significant improvement in their symptoms. The onset of effect occurred after a mean duration of  $4.28 \pm 0.75$  days (range 3–5 days). Statistically significant improvement in mean peak effect from botulinum toxin injection was  $3.7 \pm 0.48$  on a scale of 0 to 4 ( $p < 0.05$ ). The average duration of benefit was  $4.71 \pm 0.95$  months (range 4–6 months).*

**Conclusion:** *BTX-A injection is an effective therapeutic option for bruxism.*

**Keywords:** *Botulinum toxin, Bruxism, Sleep disorder.*

## Introduction

Sleep bruxism (SB) is characterized by the grinding of the teeth during sleep due to abnormal maxillomandibular activity. (1,2) It is a common and distressing disorder associated with temporomandibular pain, headaches, painful or cracked teeth and disruption of bed partner's sleep. (3,4) Various therapeutic options for SB consist of pharmacologic treatments (clonidine, clonazepam) and oral devices (mandibular advancement device, occlusal splint). BTX acts by blocking the release of acetylcholine from presynaptic cholinergic nerve endings, thus causing muscle inactivity. (5) Currently, intramuscular injection of botulinum toxin A (BTX-A) in the masseter muscle is the treatment of choice.

## Materials and Methods

This study was conducted on the patients of the Neurology outpatient department of Dr Ram Manohar Lohia Hospital, New Delhi. Based on a positive medical history and thorough examination following the ICD-10-CM guidelines of the American Academy of Sleep Medicine, probable SB was diagnosed in the patients. Patients with severe mental retardation, significant mental disabilities and tardive bruxism were excluded from the study. Patients with a history of disabling sleep bruxism refractory to medical or dental treatment were administered botulinum toxin injection. A vial of 100 mouse units (MU) of onabotulinum toxin A (Botox, Allergan, Inc., Irvine, CA) was diluted in 2 ml of saline. Prior written



informed consent was obtained from all the participants of this study. The study was approved by the institutional ethical committee.

In all patients, a dose of 20 MU of BTX-A was injected into the right and left masseters at four sites using a 0.5 mL insulin syringe (5 MU/site). The injections were given to the origin, insertion, anterior, and posterior parts of the muscle with the patient firmly clenching the teeth. (Fig1)

The evaluation was made by complaint duration, onset and duration of effect. We defined peak effect as the maximum benefit obtained from the injection; it was rated on a scale of 0 to 4 (0 = no effect, 1 = mild improvement, 2 = moderate improvement but no change in function, 3 = moderate improvement in severity and function, and 4 = marked improvement in severity and function).

Statistical analysis was done using Statistical Package for the Social Science Program (SPSS 20.0). One way analysis of variance (ANOVA) test was applied to study the differences in individual parameters. A p-value < 0.05 was considered statistically significant.



Figure 1 : Botulinum injection sites.



## Results

There were seven patients with refractory sleep bruxism included in the study (4 male and 3 female), aged 5–52 (mean age  $20.57 \pm 15.91$ ) and mean duration of symptoms  $4.71 \pm 2.81$  years (range-2-9 years). These patients had audible grinding of teeth and had damaged teeth, with difficulty in swallowing or chewing.

All seven patients reported significant improvement in their symptoms. The total BTX-A dose was 20 MU at each site. A total of 56 injection sessions of BTX - A were administered; one patient received 48 injections, three received four, two received two and one received one respectively. The onset of effect occurred after a mean duration of  $4.28 \pm 0.75$  days (range 3-5 days). Statistically significant improvement in mean peak effect from botulinum toxin injection was  $3.7 \pm 0.48$  on a scale of 0 to 4 ( $p < 0.05$ ). The average duration of benefit was  $4.71 \pm 0.95$  months (range 4-6 months). No clinical side effects were observed.

## Discussion

This study highlighted the significant reduction of pain in SB following BTX-A injections. BTX was first used by VanZandijcke and Marchau in the management of bruxism. (6) Later it was used for bruxism in association with craniocervical dystonia, autism and drug addiction. (7-9) The prevalence of bruxism is 8%-16% of the population and is often an underdiagnosed condition that not only leads to dental problems but also painful jaw, temporomandibular joint, and neck; headaches; and eventually tooth loss. (3,4)

The exact pathogenesis of bruxism is unknown; various factors such as physical or psychological stress, malocclusion, sleep disorders and drug-induced have been implicated. (9,10) Bruxism is often resistant to medical and behavioral therapy given psychogenic and neurogenic basis. There are various treatment options for bruxism, including oral splints; medications, such as muscle relaxants; antidepressants; and botulinum toxin. Multiple studies have shown that botulinum toxin injections into the masseter muscle result in relaxation of the muscles and improvement of bruxism and the pain associated with chronic clenching and grinding. (11-13) Tan and Jankovic studied 18 subjects with severe bruxism and whose mean duration of symptoms was  $14.8 \pm 10.0$  years (range three-40 years). They administered a total of 241 injections of BTX-A in masseter muscles during 123 treatment visits. The mean dose of the BTX-A was  $61.7 \pm 11.1$  mouse units, or MU (range 25-100 MU), per side for the masseter muscles. The mean total duration of response was  $19.1 \pm 17.0$  weeks (range six-78 weeks), and the mean peak



effect on a scale of 0 to 4, in which 4 is equal to total abolishment of grinding, was 3.4 +/- 0.9. Only one subject (5.6 percent) reported having experienced dysphagia with BTX-A. (13)

Lee et al. also showed improvement in sleep bruxism events following BTX-A injections. (14) Santamato et al showed improvement in neck pain associated with SB with BTX-A injections. (15) The major limitation of this study was the small sample size. Future studies with a larger sample size are required to establish BTX-A therapy in sleep bruxism.

## Conclusion

BTX-A is the most promising treatment for sleep bruxism. This case series reaffirms that therapy with BTX-A is very safe and efficacious and provides a marked improvement in sleep bruxism.

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