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Botulinum Toxin A for bruxism: a systematic review

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ABSTRACT

Objective: To systematize the scientific evidence on the efficacy of botulinum toxin type A in the treatment of bruxism. **Method:** A bibliographical search was made by researching the PubMed Central Journals and Allergan Products Literature (APL) - botulinum toxin within the last 10 years, with the following descriptors: "bruxism," "botulinum toxin," and "treatment". The methodological quality of the studies was evaluated by the Jadad Scale. **Results:** Two studies of double blind randomized clinical trials were selected. The two clinical studies showed that the application of botulinum toxin could diminish levels of pain, lower the frequency of occurrences of bruxism, and satisfy the patients in terms of efficacy of the botulinum toxin in this pathology, in addition to having no important adverse effects. Thus, the treatment with botulinum toxin type A could present itself as one possible treatment for patients with bruxism. **Conclusion:** More studies are needed that follow the quality criteria to reach a definitive conclusion about efficacy and safety.

Keywords: Botulinum Toxins, Type A, Bruxism, Pain, Rehabilitation

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INTRODUCTION

Bruxism is characterized by the parafunctional masticatory muscle activity¹ that provokes an involuntary and unconscious movement disorder, typified by excessive compression and/or grinding of the teeth, which can occur sleeping or waking.² It is one of the most difficult challenges in odontology.

Approximately 85 to 90% of the general population reports bruxism to some degree, during some period of life. The prevalence of bruxism varies between 20 and 25% in children, 5 and 8% in adults, and 3% in the elderly.

³No differences in incidence are found between males and females.⁴

Studies about bruxism are controversial, encompassing association with anxiety, stress, depression, types of personality, nutritional deficiencies (magnesium, calcium, iodine, and vitamin complexes), bad dental occlusion, inadequate dental manipulation, central nervous system dysfunction and/or disorders, use of drugs with neurochemical action, deficient oral proprioception, and genetic factors.² In recent years, a tendency to view bruxism in a much wider context has appeared: its effects may reach the neck and shoulder muscles and it is possible that they influence even the entire body posture, causing postural and/or skeletal dysfunctions.¹

Bruxism can also produce an increase in dental wear and temporomandibular dysfunction.

Delaying treatment, in some cases, may result in luxation and degenerative arthritis of the temporomandibular joint.⁵

In order to prevent these complications, the early diagnosis, as well as the appropriate treatment, are very important.⁵ The current therapies for this dysfunction are not totally effective. Seeking to present an alternative to this problem, botulinum toxin type A (BTX-A) is being studied as a therapeutic method for patients that suffer from this pathology.

OBJECTIVE

To systematize the scientific evidence on the use of botulinum toxin type A in the treatment of bruxism.

METHOD

In May of 2013, a systematic review technique was used in order to select the publications and identify randomized and controlled clinical trials on the use of botulinum toxin for bruxism. The bibliographical search was made through the PubMed Central Journals and Allergan Product Literature (APL) - botulinum toxin databases encompassing the last 10 years, with the keywords bruxism, botulinum toxin, and treatment. Two researchers made the search independently and subsequently confronted the results.

The articles were selected by their abstracts and, to be included in this study, they had to be randomized clinical trials, published in Portuguese, English, or Spanish. Studies were excluded if they obtained scores lower than 3 according to the Jadad quality scale.⁶

RESULTS

The bibliographic search resulted in 228 articles (57 from the PubMed Central Journals and 171 from the Allergan Product Literature - botulinum toxin). After excluding the repeated articles, those that did not discuss clinical studies in patients, and those that did not discuss only bruxism as the main pathology, there were six articles left. After a complete evaluation of the six articles mentioned, only two had reached scores equal or higher than 3 according to the Jadad quality scale (Chart 1). In the end, two double-blind randomized studies were included in this systematic review. Details of both studies are shown in Chart 2.

The age of the participants in the studies varied from 20 to 45 years and the size of the sample varied from 12 participants³ to 20 participants.

⁸ Both studies used saline solution as a placebo.^{3,8}

Lee et al.³ compared the efficacy of botulinum toxin with the placebo in reducing the frequency of bruxism events after the application (4, 8, and 12 weeks after the application) in 12 patients with bruxism. Those authors injected 80UI of botulinum toxin A (Dysport®) at three points in both masseter muscles in six patients, comparing them with the other six patients who received applications of saline solution. They observed that the patients

treated with botulinum toxin showed a significant reduction of the masseter muscle electromyographic activity and clinical improvement of bruxism, while the temporalis muscle activity was not altered. Through electromyography (EMG) it was detected that the bruxism was significantly less frequent in the group that received the botulinum toxin A than in the group that receive the placebo. Their results suggest that the botulinum toxin reduces the number of bruxism events by reducing muscle activity, concluding that it is an effective treatment for nocturnal bruxism.

Guarda-Nardini et al.⁸ compared the efficacy of botulinum toxin with the saline solution in the reduction of pain in 20 patients with bruxism and myofascial pain in the masticatory muscles. The pain levels at rest and in mastication were evaluated through the visual analogue scale (VAS) in the interval of 0-10, before and after the application with botulinum toxin. The authors injected 30UI of botulinum toxin type A (BOTOX®, Allergan) at three points in the masseter muscles and 20UI at two points in the anterior temporalis muscles of 10 patients with myofascial pain associated with bruxism, and they used saline solution on the remaining selected patients. They observed that the degree of pain reduction in mastication, over the course of six months of follow-up, was significantly greater in the botulinum toxin group than in the placebo group.

Both studies reported different objectives for the treatment of bruxism with botulinum toxin. Therefore, they differ in the standards used to evaluate efficacy: Lee et al.³ employed, in addition to electromyographic evaluation, a questionnaire on bruxism, while Guarda-Nardini et al.⁸ used the VAS to monitor the pain symptoms. Thus, their results should be analyzed separately.

Lee et al.³ reported that the subjective evaluation of botulinum toxin efficacy did not differ between the groups 4, 8, and 12 weeks

Chart 1. Quality evaluation of the clinical studies previously selected, according to the Jadad scale

Randomized study
Adequate Randomization
Double-blind study
Masking was adequate
Description of losses and exclusion
Jadad Score

Lee et al.³ Yes No Yes Yes Yes 3

Alonso-Navarro et al.⁷ No No No No No 0

Guarda-Nardini et al.⁸ Yes Yes Yes Yes No 4

Readelli et al.⁹ No No No No No 0

Sener et al.¹⁰ No No No No No 0

Bolayir et al.¹¹ No No No No No 0

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efficacy in the application of BTX-A in application only to the masseter, suggesting that maybe it is not necessary to apply it as well to the temporalis muscle to treat bruxism.

Sener et al.¹⁰ showed a controlled study

of two phases with 13 patients. In the first phase, the patients used intraoral plates (two months) and after a period without the plate (two months), they received 60UI of botulinum toxin type A (BOTOX®, Allergan) in the masseter muscle on both sides. Those authors affirmed that the intraoral plate and the BTX-A were equally efficacious treatments for bruxism. However, the BTX-A could be a more efficacious alternative for patients with bruxism and, many times, more effective, since there is no need for the patient to cooperate in using it every day, as is the case with the intraoral plate.

Other authors also report good results with the use of botulinum toxin for bruxism,^{7,9,10,11} showing it to be an alternative treatment to be better studied as a treatment for these patients.

CONCLUSION

Bruxism presents a broad etiology, the gravity of damage tends to vary with each individual, and the more the patient is aware of this habit, the better the prognosis and more motivated the patient will be. Therefore, it is necessary that the health professional clarify the patient on the relationship between the parafunctional habit and its triggering factors.

Both clinical studies show that applications of botulinum toxin can reduce the levels of pain, the frequency of bruxism events, and satisfy the patients in regard to the efficacy of botulinum toxin in this pathology, and without provoking important adverse effects. The muscles to be injected are the masseter and the temporalis anterior (Figure 1).

Thus, according to the two studies discussed above, 30UI of BOTOX® or 80UI of Dysport® in each masseter and 20UI of Botox in each temporalis is the recommended dosage. The patient should be evaluated 15 days after the application and return for control after three or four months after the application for a new evaluation and another application, if needed. In this way, the treatment of bruxism with botulinum toxin type A can present itself as a possible treatment for bruxism patients. More studies are needed that follow the quality criteria to reach a definitive conclusion on safety and efficacy.

Chart 2. Methodological characteristics of the selected studies on the use of botulinum toxin in the treatment of bruxism

Item Lee et al.; Guarda-Nardini et al.^s
Methodological

design

Double-blind randomized

Controlled clinical trial

Double-blind randomized

Controlled clinical trial

Sample

6 + 6 (20-30 years)

Follow-up: 4, 8, and 12 weeks

Follow-up rate: 100% of the cases

10 + 10 (25-45 years)

Follow-up: 1 week, 1, and 6 months

Follow-up rate: not reported

Treatment

Group 1: 80UI Dysport (0.8 mL) in each masseter

Group 2: 0.8 mL (saline solution) in each

masseter

Group 1: 30UI Botox in each masseter

20UI Botox in each temporalis anterior muscle
Group 2: saline solution
Efficacy Significant reduction in the frequency of bruxism
when compared with saline solution
Significant reduction in pain and subjective
efficacious improvement when compared with
the group that received saline solution
Safety No adverse effects Not reported

after the applications. Guarda-Nardini et al.⁸ reported that the subjective evaluation of botulinum toxin efficacy did not differ between the groups one week and one month after the injection, but it was significantly greater in the botulin toxin group than in the placebo group six months after the application. Of the two studies included, one⁸ did not report on the adverse effects of the botulinum toxin applications and the other³ reported no adverse effects to the application.

DISCUSSION

Due to different taxonomies and diagnostic aspects, there is some difficulty in determining an acceptable standardization of diagnosis for bruxism.¹² The American Academy of Sleep Medicine defines bruxism as a stereotyped oral and motor sleep disorder characterized by the teeth grinding and tightening, while the American Academy for Orofacial Pain extends the definition to the same movements that occur in the waking state.¹³ Intramuscular applications of BTX-A are an effective treatment for a variety of movement afflictions.¹⁴ They inhibit the exocytotic release of acetylcholine in the motor nerve terminals leading to reduced muscle contraction. This property makes it useful both clinically and therapeutically for a series of conditions where there is an excess of muscle contraction.¹⁵

Recent advances show that bruxism is caused by high levels of motor activity in the centrally situated mandible musculature, indicating that the reduction in muscle activity induced by the use of BTX-A could be beneficial in these cases.¹⁶

This suggests that the application of botulinum toxin type A reduces the number of bruxism events, probably due to the diminishing of peripheral muscle activity,^{3,9,11} without presenting an action on the central nervous system.¹³ The adverse effects of this treatment are irrelevant or nonexistent.^{3,7,9,11} The most common side effects are dry mouth and smile alteration. The BTX-A effect is related to the location of the application and the dosage.¹⁷ In the application of botulinum toxin type A, the maximum therapeutic action is observed between the 7th and 14th days and the effects may last as long as six months (average of 3 to 4 months).¹⁸ Problems may be found related to the lack of efficacy in muscle relaxation due to the use of improper dosage, technical error in the application of the product, resistance to BTX-A, or alterations in the product or inappropriate storage conditions of BTX-A.¹⁷

The use of botulinum toxin in pathologies that are accompanied by movement disorders showed benefits in other clinical aspects

such as relief of the concomitant painful conditions. The studies by Bolayir et al.¹¹ and Sener et al.¹⁰ also reported the efficacy of the botulinum toxin in improving sensitivity in the masticatory musculature of the participating patients. It is seen that therapies with dry needling, when performed correctly and with due care, are among of the most effective options to treat myofascial pain, the result presented by Guarda-Nardini et al.⁸ could be due to the needling itself and not to the botulinum toxin. There are, however, works reporting that the application of botulinum toxin could be more efficient than dry needling in some cases.¹⁹

The two works included in this review show the efficacy of botulinum toxin to treat bruxism in applications to the masseter and temporalis muscles both,⁸ or to only the masseter.³ As for the points of application, the BTX-A was applied at three different points in the masseter^{3,8} and at two points in the anterior temporalis.

⁸Through the literature, one observes the

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Figure 1. Points of application of botulinum toxin, according to the literature mentioned

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