Botulinum Toxin on The Reduction of Pain and Bite Force for the Management of Bruxism - Randomized Clinical Study

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INTRODUCTION

Bruxism is an oral habit consisting of involuntary and unconsciously rhythmic or spasmodic nonfunctional gnashing, grinding, or clenching of teeth, either while awake or during sleep. If not treated, it leads to damage of the teeth, periodontium and oral mucosa, pathology of the muscles constituting the masticatory system, headache and cervical pain, temporomandibular, and hearing disorders (1, 2, 3).

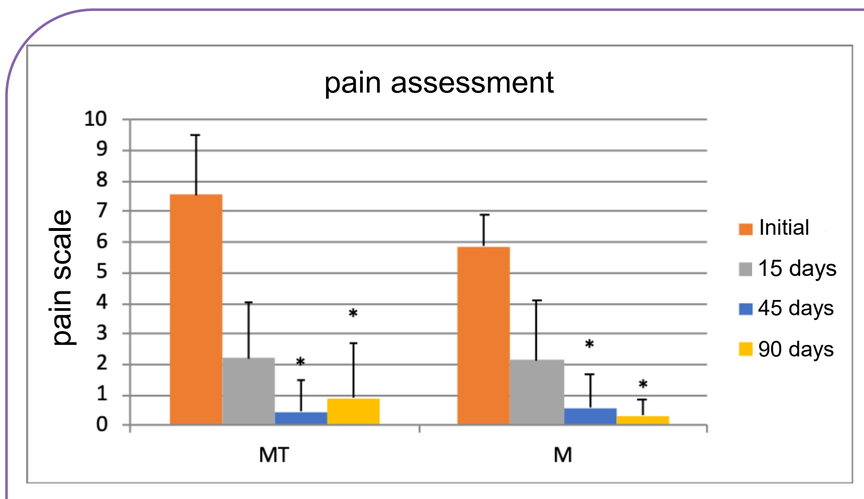
Modalities of treatment for the management of bruxism have been investigated, such as: occlusal splints, drugs,and cognitive-behavioral therapy (4), however, such therapies have not been shown to be completely effective, leading to search for new treatments options.

In order to expand these therapeutic and pharmacological possibilities, injections of botulinum toxin type A (BTX-A), in the masseter muscles (5,6) or in the temporal and masseter muscles (7,8), was recommended for the management of bruxism.

OBJECTIVES

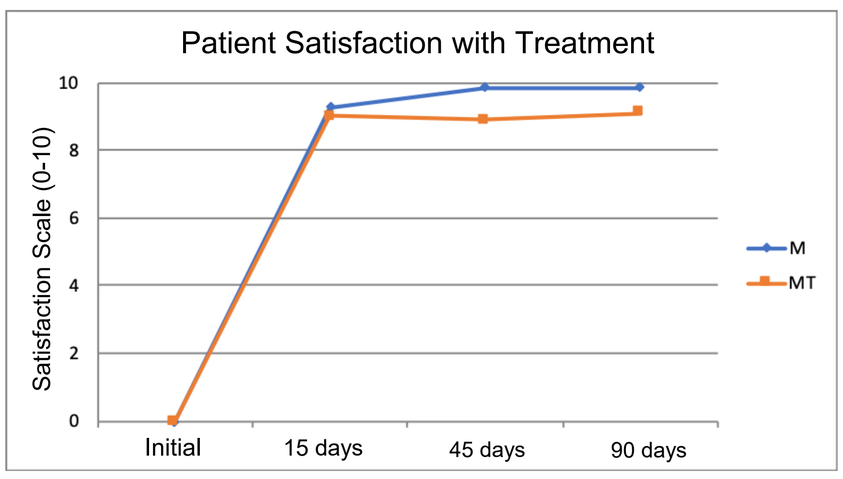
To compare, through a randomized controlled clinical trial, the patient's perception of pain/discomfort reduction, before and after the application of TBX-A, as well as to evaluate the quality of life, satisfaction, sleep quality and the durability of the effect of BTX-A on bite force under two different injections application strategies (group TM - masseter + temporal muscles and group M - masseter), in the management of bruxism, with the aim of establishing safer and more effective therapeutic protocols.

RESULTS



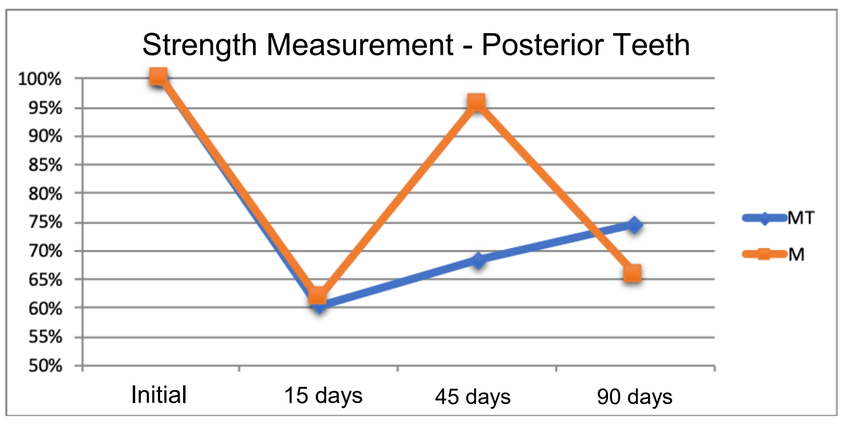
MT: Masseter and Temporal Group; M: Masseter Group;
* indicates statistically significant difference in relation to the initial value of the respective group.

There was no statistical difference between any time between groups. Within each group, a statistically significant difference can be observed in the reduction of pain reported by the patient at 45 days and 90 days compared to the initial value ($p<0.05$). There was no difference in the time of 15 days in any of the groups (M, MT) in relation to the initial value.



Satisfaction values reported by patients at 0 days (initial), 15, 45 and 90 days after botulinum toxin application.

There was no statistically significant difference between groups M and MT in any of the evaluated times ($p>0.05$). There was a statistically significant difference on days 15, 45 and 90 days compared to the initial values of each group ($p<0.05$), showing that from 15 days to 90 days, patients in both groups maintained their degree of satisfaction.



The 15-day reduction in bite force compared to baseline was significant in both groups. In the TM group, bite force was reduced after the intervention and was maintained throughout the reassessments, with a gradual return of force. In group M there was a significant increase in strength at the 45-day reassessment and again a reduction in the 90-day assessment

METHODS & MATERIAL

The study was approved by the Ethics Committee and registered: www.ensaiosclinicos.gov.br

This randomized blind clinical trial was conducted by 01 operator with the following criteria: patients with complaints of pain, wakefulness or sleep bruxism, and who also presented cephalgia/chronic orofacial pain, pain on palpation of orofacial muscles, aged between 18 and 70 years , of both sexes. Exclusion criteria were: individuals with known allergy to BTX-A, pregnant women, wearers of an oral removable device, orthodontic appliances or those with missing teeth in the area to be edentated by the gnathodynamometer. The randomization sequence was generated (www.sealed envelope.com) and the allocation was ensured with the use of opaque envelopes, sealed and numbered in series and kept by an independent researcher.

The final sample consisted of 20 participants divided into two groups (10 participants in the MT group and 10 participants in the M group).

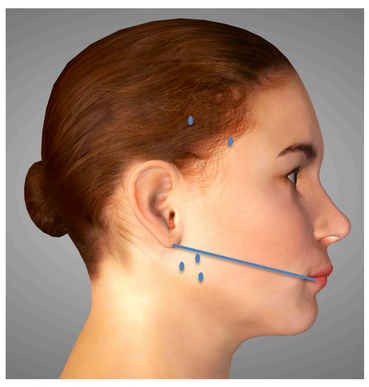
Group M (experimental): BTX-A in masseter muscles bilaterally (3 points).

MT group (control): BTX-A in masseter muscles bilaterally (3 points) and temporal (2 points) bilaterally.

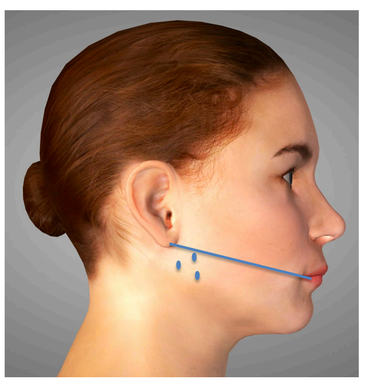
Pain and discomfort assessment using a modified Visual Analogue Scale for pain (VAS).

The occlusal force was measured using a gnathodynamometer (DMD model, Kratos Equipamentos Industriais Ltda, Cotia, SP, Brazil).

Participants were asked about their satisfaction with the treatment performed (0 to 10).



MT GROUP - Application points related to the masseter and temporal muscles



GROUP M - Application points related to the masseter muscles

gnathodynamometer (DMD model, Kratos Equipamentos Industriais Ltda, Cotia, SP, Brazil).

CONCLUSION

In patients with bruxism, the use of BTX-A has been shown to have a positive effect related to a decrease in bite force intensity, which coincided with a decrease in the level of pain, improvement in quality of life and, in addition, it had a high degree of satisfaction of the evaluated patients.

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