Standardized use of Botulinum Toxin A in patients with bruxism: results on a consecutive series of 120 patients

A. Redaelli, M.D., Milan

Abstract

Background: the therapy of bruxism is today still scarcely efficient. The use of BTA can be very helpful in the majority of patients who suffer from bruxism, without any major side effects.

Materials and methods: from January 2009 to January 2010, 120 patients have been treated. No particular exams were required. They have been treated with Botulinum Toxin A (BTA) in the masseter muscle with standardized dosages and injection spots. Patients have been seen again 15 days after the procedure and have filled in a satisfaction test. 23 patients have been reinjected with more doses of BTA for insufficient results. Subjective results and side effects have been evaluated.

Results: all the patients declared a good/very good improvement of the symptomatology. No important side effects have been reported. In the end, 36 patients (30%) declared a discreet result, 79 (65.8%) good and 5 (4.2%) excellent.

Conclusion: Botulinum Toxin A represents a very easy method of treatment for Bruxism, without important side effects and it pleased patients. It still needs objective studies to determine the actual effectiveness on the target structure of the pathology, in particular the teeth.

Introduction

Bruxism is one of the most diffused parafuncitons that afflicts an unknown but surely more than the 15% of the population (2,3). We divide in daytime bruxism, more common despite what the majority of doctors thinks, and the nocturnal bruxism, less common (4). It is an involuntary activation of the masticatory muscles with excessive strength. In fact, a nocturnal activity of slight grinding teeth is very frequent and it is not consider as a real pathology.

There are three major etiological causes:

1) interferences and occlusal pre-contacts for ununiformity of dental surfaces (2,7)

2) the use of many medicines for people who often have involuntary movements (2,8)

3) stress (10,11), the most recent and confirmed theory. In personal predisposed conditions, working and emotional stresses tend to arouse parafunction (very similar to the starting of other parafuncions, in particular onychophagy).

The therapy of bruxism is still not exactly defi ned (5,8,10,11) and people who work on it, especially dentists, know that both plaques and splints or bites and even all the other psychological therapies that tend to contain the stress, are scarcely effective and do not last. If is difficult to take care of the cause that arouse the muscular activity, it is instead very easy to modulate the activity. This idea brought to the use of Botulinum Toxin A (BTA) that has been already approved for the correction of this pathology, but with very variable dosages (5,6,7).

So, it has been standardized a dosage of BTA that is efficient in the majority of patients. After an initial time during which the temporo-mandibular Electromyography has been used (1) to document the results, the author started to treat their own patients, who suffer from bruxism after a precise anamnensis that documented the presence of this parafunction, with standardized dosages of BTA, without the use of EMG.
Results were encouraging and no important side effects were reported. Aim of this publication is the revision of the casistic to evaluate the real benefits and connected risks.

**Materials and methods**

From January 2009 to January 2010, 120 patients have been treated, 106 women and 14 men. All the patients contacted the doctor for aesthetic reasons, for the treatment of the glabella wrinkles (9). All the patients, who had the treatment with BTA for wrinkles, were asked if they suffered from Bruxism, and they were treated because the diagnosis had been previously done. All the patients read the informed consent in which it was highlighted how the treatment of BTA for the masseter muscles were “Off Label”, as for the treatment of the wrinkles outside the glabella area. All the patients understood the particularity of the treatment and accepted the procedure.

![Pic. 1: in a) a syringe of 0,5 ml used on daily bases and in b) the detail that highlights the unit of Vistabex contained exactly in 0,02 ml](image)

We used Botulinum Toxin A (Vistabex 50 U, Allergan, Irvine California). These units have been diluted always with 1 ml of physiological solution. So 0.02 ml exactly contains 1 unit (Pic. 1b). For the injections we used always a syringe of 0.5 ml for diabetes, Becton Dikinson, with a fixed needles of 30G x 8 where the units of the toxin are clear and easily measured (Pic. 1a).

![Pic. 2: in a) spots of injections are highlighted while in b) a syringe before the injection. Notice the good visibility of the unit to inject.](image)
All the patients have been drawn before the treatment to better define the masseter muscle and draw the three spots of injection (Pic. 2a). The injection has been executed perpendicular to the skin directly in the muscle (Pic. 2b). It has been asked to patients to subjectively evaluate the result after 15 days with a scale from 0 to 4 (0=null, 1=scarce, 2=discreet, 3=good, 4=very good).

The first 20 patients out of 120 treated, received a dosage of 8 U for each side divided in 3 injective spots (2+2 on the mandibular edge and 4 in the upper spot). After 15 days, 2 of them referred to good results, the remaining 18 a discreet (from 1 to 2). They were retouched with 6 U (2+2+2 in the three classical spots for a total of 14 U from the first and the second session). They have been seen again after 15 days and reported a discreet result and in one case excellent. They were not retouched again.

Since then, all the following patients (100) were treated with a standardized dose of BTA of 14 U (4+4 on the mandibular edge and 6 on the upper spot). 32 of these patients (26,6%) declared a discreet result, 59 (49,1%) a good result, while 4 of these patients (3,3 %) declared very good results. These patients were not retouched. 5 patients (4,1 %) said they had a scarce or null effect to the therapy and for this reason they have been treated with 2U for each injective site (20 U total for the first and second session). They have been seen again after 15 days, only one patient declared a good result, while the other 4 still declared a scarce result. They have not been retouched.

Out of 120 patients, 78 (65 %) came back again, after 4-6 months. 42 of them were not seen (both because they got lost or because the treatment is premature since it cannot be repeated more than every 4 months). Out of the 78 patients, all of them returned for the aesthetic part but 68 (87,1 %) wanted to do again the treatment of the masseter, which has been redone with the total dosage of the previous session.

<table>
<thead>
<tr>
<th>Number of Patients</th>
<th>%</th>
<th>Used Units (for side)</th>
<th>Definitive Score Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total of Patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>1,6</td>
<td>8U in one session</td>
<td>2 pat (1,6 %) - 3</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>6U in the second</td>
<td>17 pat (1,4 %) - 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>session (14U total)</td>
<td>1 pat (0,8 %) - 4</td>
</tr>
<tr>
<td>100</td>
<td>79,1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>14U in one session</td>
<td>32 pat (26,6 %) - 2</td>
</tr>
<tr>
<td></td>
<td>59</td>
<td>14U in one session</td>
<td>59 pat (49,1 %) - 3</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>14U in one session</td>
<td>4 pat (3,3 %) - 4</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>6U in the second</td>
<td>1 pat (0,8 %) - 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>session (20U total)</td>
<td>4 pat (3,3 %) - 1</td>
</tr>
</tbody>
</table>

Tab. 1: number of treated patients, injected units and obtained results

**Results**

All the patients declared not to have had major side effects. In particular no problem of chewing, deglutition while drinking and eating or any other sensation were referred.

Out of the 120 patients treated, only 2 (1,6 %) declared a good result (score 3) with 8U. The majority of patients (113 = 94,1%) declared a result that goes from discreet to very good with 14U: none declared a null or scarce result, 32 patients declared a discreet result, 76 good and 5 patients very good with a disappearance of painful symptoms in particular in the morning when they wake up, with a sensation of relaxation completely different from the past.

5 patients treated with 14U declared an insufficient result and for this reason they have been retouched with 6 more units. The result improved in a patient while in the other 4 remained the same.
In conclusion, out of the consecutive 120 patients treated, in the end 4 (3.3 %) patients declared they had a scarce result, 32 (26.7 %) discreet, 79 (65.8 %) good and 5 (4.2 %) very good.

Discussion

Botulinum toxin A revealed to be in these past few years an extremely efficient medicine and, if well used, free from major side effects. The results on our patients were more than encouraging. There is a minority who however did not improve extraordinarily and this is probably due to the fact that this bruxism does not depend, in a relevant way, on the hypertone of the masseter.

The majority of positive results induce to think that the masseter remains a muscle involved in the bruxism and it is possible to have good results event with no preventive tests.

In fact, according to the author, the diagnosis of bruxism has already been done before in the majority of patients and further tests are often useless.

The best dosage seems to be the one with 14U for each side, but in people with strong muscles, 20U could be more efficient, and however there are not major side effects.

It seems there are not important differences between the treatments in one or two sessions.

In the end, the high percentage of patients who wanted to repeat the treatment after few months, appreciated the procedure.

Increasing the dosage, as some authors do (4,5,6), seems to be useless in the majority of patients.

Conclusions

Bruxism still remains a very diffused pathology among the industrialized countries and sometime it is invalidating. Its treatment with Botulinum Toxin A after the revision of our casistic, revealed to be very efficient in reducing the subjective symptoms in particular in the morning. Further studies have to confirm even the reduced impact of the parafunction on the target organs, in particular the teeth. A further application can be its use to reach a minor tension in anticipation of particular dental therapies as the first bone implants.

Bibliography


3) Lavigne GJ: et all Restless legs syndrome and sleep bruxism: prevalence and association among Canadians: Sleep 1994; 17: 739-743


7) Palla, S. (2001), Mioartropatie del sistema masticatorio e dolori orofacciali, Milano, RC Libri srl


9) Redaelli A: La medicina estetica See-editrice Firenze, 2009


Contacts: www.docredaelli.com mail@docredaelli.com