Botulinum Toxin A in bruxers.

One year experience

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ABSTRACT

الأهداف: دراسة وتقييم فوائد البوتوكس من النوع أ (الذيفان البوتيليني) في علاج صريف الأسنان (Botulinum)، بالإضافة إلى دراسة نتائجه، وآثاره الجانبية.

الطريقة: أُجريت هذه الدراسة الاسترجاعية خلال الفترة من يناير 2009م إلى يناير 2010م، وشملت 120 مريضاً مصاباً بصريف الأسنان وقد تمت معالجتهم من دون إجراء أياً من الفحوصات وذلك لأن التشخيص كان معروف مسبقاً. لقد تمت معالجة المرضى بحقن البوتوكس في مواضع محددة وبجرعات مدروسة في العضلات الماضغة. وبعد مرور 15 يوماً تمت معاينة المرضى، بالإضافة إلى تقييم مدى رضاهم عن العلاج بواسطة استبيان مختصر. لقد أُعيد حقن جرعات إضافية من العلاج إلى 23 مريض لأن النتائج كانت غير مرضية، وتم تقييم النتائج الشخصية والآثار الجانبية أثناء الدراسة.

النتائج: أشارت النتائج إلى أن كافة المرضى أعربوا عن رضاهم عن العلاج حيث كانت نسبة التحسن جيدة أو جيدة جداً. ولم يتم ملاحظة أياً من الآثار الجانبية، وفي نهاية الدراسة كانت نتائج العلاج متوسطة في 36 مريضاً (30%)، وجيدة في 79 مريضاً (65.8%)، وممتازة في 5 مرضى (4.2%) وذلك اعتماداً على التعليقات التي أبداها المرضى.

خاتمة: أثبتت الدراسة مدى فعالية البوتوكس من النوع أ (الذيفان البوتيليني) وبساطته في علاج صريف الأسنان، كما أن ليس له آثاراً جانبية ويعد مقبولاً من قبل المرضى. تحتاج مثل هذه الطريقة في العلاج المزيد من الأبحاث من أجل دراسة آثار العلاج على العضلات والأسنان وذلك على المدى الطويل.

Objectives: To review and assess the benefits, outcome, and side effects of using Botulinum Toxin A (BTxA) in the treatment of bruxism.

Methods: From January 2009 to January 2010, 120 bruxers were treated; no special examinations were carried out, since the exact diagnoses were made beforehand. All were treated with BTxA in the masseter muscle with standardized doses and injection sites. A follow-up examination was made 15 days post-procedure, and all patients responded to a short satisfaction questionnaire. Twenty-three patients were re-injected with additional doses of BTxA for insufficient results. Subjective results and side effects were assessed.

Results: All patients have declared a good/very good improvement in symptoms. No significant side effects were seen. At the study's conclusion, 36 patients (30%) declared a fair result, 79 (65.8%) good, and 5 (4.2%) excellent.

Conclusion: Botulinum Toxin A is a simple method of treatment of bruxism, without side effects and appreciated by patients. The technique needs further studies to assess long-term outcome on target structures, especially on teeth.

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Bruxism is one of the most widespread parafunctions in the world. The number of those afflicted is actually unknown, but it certainly exceeds more than 15% of the population.[1] We distinguish between daytime bruxism, which is more widespread, as opposed to what most doctors think, and the less common night-time bruxism,[2] which is an involuntary activation of chewing muscles with excessive force. A light activity of clenching and chewing during the night is common and does not classify as a true disease.[2] There are 3 main etiological causes of this parafunction;[1-6] the interference and occlusal pre-contacts for dental disuniformity, the use of many neuroleptic and antipsychotic drugs, as all of these drugs are used in individuals who are prone to involuntary movements, and stress,[5] which is currently the most accredited theory. In predisposed persons, stress

and emotion tend to trigger the parafunction (very similar to other parafunctions, especially onychophagy). Bruxism treatment has not yet been precisely defined,[4-6] and the experts, dentists particularly, are well aware that plaques, splints, or bites, as well as the psychological stress-reduction therapies, are often ineffective and do not provide long-lasting results. While it is a challenge to reduce the causes that provoke this abnormal muscle activity, on the other hand, it is easy to reduce its frequency and potency with the use of Botulinum Toxin A (BTxA), which has already been proposed for the correction of this particular problem, but with variable, and often excessive doses.[7-11] Therefore, a standardized dosage of BTxA has been found, which has proven effective in the vast majority of patients. The purpose of this publication is to review our case histories and assess the real benefits and risks of the use of BTxA in the treatment of Bruxism.

Methods. This retrospective study includes Bruxism patients, and complied with the guidelines of the Helsinki Declaration, especially regarding patient confidentially, and ethical approval was obtained when needed.

From January 2009 to January 2010, among all the patients that arrived to the practice for esthetical problems of the glabellar wrinkles,[10] (the label indication of BTxA in Italy), we treated 120 patients for bruxism (106 women, and 14 men). The criteria for inclusion of these patients also for the treatment of bruxism, were a complete and previously made diagnosis of this parafunction. No further examinations were made. In the first session the question: "are you a bruxer?" was posed to every patient. These 120 patients answered immediately affirmatively, since they were complete aware of the diagnosis. The criteria for exclusion were a not completely previously made diagnosis, all non bruxer patients and standard contraindications to the BTxA treatment. All patients read and signed an informed consent, which highlighted that in Italy treating masseter muscles with BTxA is an "off label" indication, as is the treatment of wrinkles outside the glabellar region. All patients understood the particularity of the treatment and accepted the procedure. We used BTxA (Vistabex 50 u, Allergan, Irvine California). The vial is diluted with 1 ml of physiological saline solution; So, 0.02 ml contains exactly one unit. For the injections, we used a 0.5 ml syringe for diabetes Becton Dickinson with a fixed needle 30 G x 8 mm. All patients were marked prior to treatment, to assess the exact points of injection in the masseter muscle and the injection was made keeping the syringe at a perpendicular position, directly in the muscle (**Figure 1**). After 15 days, all patients were asked to evaluate the subjective result in a scale from 0 to 4 (0=no result, 1=scarce, 2=fairly good, 3=good, and 4=excellent). Among the 120 patients treated, the first 20 were injected with 8 U x side (3 injection sites: 2U + 2U on the mandibular edge and 4U in a point above). Of these patients, all followed up on the fifteenth day, 2 reported a good result, while 18 reported a lower result (score between 0 and 1), and were therefore adjusted with another injection of 6U (2+2+2U in the 3 classic points for a total of 14U after the first and second session. On review after a further 15 days, 17 patients declared a fairly good result, and excellent in one case; none of who were injected further. Since then, all the following patients (100) were treated with a standardized starting dose of 14u of BTxA per side (4+4U on the mandibular edge and 6 in the higher point) (result scale from 2 to 4). These patients have not been retouched. Five of these patients (4.1%) declared a result score from 0 to 1 and for this reason, were treated with 2u for each injection site (a total of 20U after the first and second session). After a 15-day follow-up period, only one declared a good result while the other 4 still acclaimed the result to be scarce. Of 120 patients treated, 78 (65%), after a period ranging from 4-6 months, have continued the therapy, while 42 (35%) have not yet been evaluated (either because they were "lost" or because the last treatment is still too recent and must not be made before at least 4 months have passed). Of the 78 patients, all have returned for the aesthetic indication but 68 (87.1%) of them wanted to re-inject the masseter muscle as well, which was re-injected with the total dose of the previous session.

Results. No patients remarked on any important side effects. Problems with chewing or swallowing while drinking or eating, or other sensations generally classified as unpleasant, were not reported. Of 120 patients treated, only 2 (1.6%) declared a good result (score 3) with 8 U per side. The other 18 patients treated with only 8U per side declared a poor result, and for this retouched with 6 U more. 8 U per side are not enough to

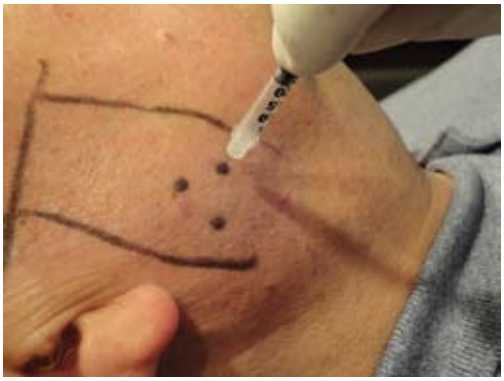

Figure 1 - Direction of the syringe, directly in the muscle.

have good results. Most patients (113 patients, 94.1%) declared a fairly good to excellent result (score 2 to 4), when injected with 14 U per side and in particular: no patient declared no or a poor result, 32 (26.7%) declared a fairly good result, 76 (63.3%) good, and 5 (4.2%) patients even had an excellent result with great pain relief, especially upon awakening in the morning, a feeling of relaxation significantly different from previous experience. Five patients treated with 14 U declared an insufficient result, and were therefore retouched with another 6 U per side. The result improved to "good" in only one patient, while in the other 4 (3.3%), the result apparently remained unchanged (scarce). Among all the 120 consecutive patients treated, 4 (3.3%) patients declared scarce result, 32 (26.7%) fairly good, 79 (65.8%) good, and 5 (4.2%) excellent.

Discussion. Over recent years, BTxA has proven to be an extremely effective drug if well used, without any significant important side-effects.[7-11] In our case study, most of the patients declared positive results, which suggest that the Masseter muscle is almost always most responsible for bruxism, and that good results are present, even without special exams prior to the procedure. A small minority declared poor results, because in these particular patients, bruxism probably resulted from a hyper-tonicity also of other masticatory muscles. In fact, if the patient has already been diagnosed with bruxism, additional tests are unnecessary, and patients can be treated with standardized doses without any further diagnosis. The best dosage seems to be 14 U per side, but when treating patients with powerful muscles, even 20 U for each muscle could be the most effective dosage, without any side effects. There were no significant differences between one and 2 sessions. Finally, the high percentage of patients who chose to repeat the treatment months later, proves the high satisfaction rating of the procedure. Larger dosages, as proposed by some authors[7,9,11] seem to be useless in most patients.

Botulinum Toxin A appears to be very effective in treating chronic facial pain associated with bruxism. In Von Lindern's study casistic,[9] 91% of patients treated with BTxA had a significant improvement of symptoms, with much better results than patients treated with a placebo. While our percentage of excellent results was not as large, most of our patients declared a good overall improvement. As in all other reported scientifical studies casistics, there were very few side effects, which is another reason BTxA remains a very safe treatment.[7-11] Our case study also confirms this, as we did not have any important side effects.

In conclusion, Bruxism continues to be a widespread pathology among the population of industrialized countries and may sometimes be very debilitating. Its treatment with BTxA, after the revision of our study, proved to be very effective in reducing subjective symptoms especially during the night and on awakening in the morning. Our results have been very encouraging, and further studies are needed to confirm the reduced impact of this parafunction on target organs, in particular the teeth. A further application may be its use to reduce clenching and chewing in all those patients who must undergo dental therapies, prior to bone implants, or "Immediate Load" dental implants.

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