Occlusal force characteristics of masseteric muscles after intramuscular injection of botulinum toxin A (BTX – A) for treatment of temporomandibular disorder

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Abstract

Our aim was to evaluate the occlusal force and therapeutic efficacy of the masseteric muscles after intramuscular injection of botulinum toxin A (BTX-A) for the treatment of patients with concurrent temporomandibular disorders (TMD) and bruxism. Thirty patients with TMD associated with bruxism were randomised into three groups (n = 10 in each group), and treated by bilateral intramuscular injection of BTX-A into the masseter, placebo, or control. We used an occlusal force analysis system to collect several measures of occlusal force such as duration of biting and closing, the maximum occlusal force, and the distribution of occlusal force. The occlusal force in the intercuspid position was reduced in all three groups. There was a significant difference between the BTX-A and placebo groups (F(df = 1) = 8.08, p = 0.01) but not between the control group and the other two (F(df = 1) = 4.34, p = 0.047). The duration of occlusion was significantly increased in the BTX-A group after 3 months’ treatment (t = 4.07, p = 0.003). The asymmetrical distribution of occlusal force was reduced in all three groups, but not significantly so (Levene’s test F(df = 2) = 0.25, p = 0.78, ANOVA F(df = 2) = 0.50, p = 0.61). Treatment of TMD with BTX-A is effective in reducing the occlusal force, but psychological intervention plays an important part in treatment.

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Keywords: botulinum toxin A (BTX-A); psychological intervention; T-scan; bruxism; TMD

Introduction

Temporomandibular disorders (TMD) are common throughout the world, and cause local pain and dysfunction of the joint. The causes include psychosocial and social factors, anatomy of the jaw, immune disorders, overloading of the temporomandibular joint, and trauma. There are several treatments available, and the most commonly used are physiotherapy, splinting, injection of drugs, arthroscopy, and operation. Patients often prefer conservative treatments such as physiotherapy, psychosocial intervention, and splinting, which are non-invasive, painless, and cost little, but they require good compliance to be effective. Drug treatment is more effective and acceptable, and requires less compliance than conservative treatments. However, it requires an acceptable level of health, and is sometimes restricted because the drug is contraindicated. Arthroscopy and surgery are less acceptable for both clinicians and patients because they are invasive and expensive, and there must be strict indications for surgery.

Botulinum toxin A (BTX-A), a neurotoxin, is widely used to treat muscle spasms, facial twitching, salivation, and myofascial pain as it has a muscle-relaxing and possible antinociceptive effect. We hoped that its muscle-relaxing
effect would reduce occlusal force in the treatment of patients with TMD.

The occlusion analysis system is a computer-assisted dental device with a pressure sensor. It was developed in 1984 to measure occlusal forces and contact times, and is considered a prosthodontic adjunct specific to problems that develop during the treatment of occlusal disorders and TMD. Koos et al. showed that it was both accurate and stable, and neither changing the foil nor repeated measurements had an appreciable influence on the measured value. It is able to show any alteration in the distribution of occlusal force during occlusion, and provides technical guidance for its clinical use.

To date, we know of few (if any) studies that have described the outcome of injection of BTX-A into the masseter muscle for treatment of TMD, and comparison of characteristics such as occlusion time during treatment and distribution of occlusion have not to our knowledge been investigated. Our hypothesis, therefore, was that BTX-A can reduce occlusal force and so is more effective than isotonic saline for the treatment of patients with concurrent TMD and bruxism.

Material and Methods

Selection of patients

Thirty patients with TMD and bruxism were enrolled from October 2013 to August 2014 at the Shanghai Sixth People’s Hospital Dental Clinic. The criteria for inclusion were: patients with subjective symptoms (pain, snapping, or limited mouth opening) who were diagnosed with TMD; complete permanent dentition; bruxism or history of daytime clenching for more than two months; electromyographic activity of the masseter at the mandibular posture position >0.1 mV, and at the intercusp position <1 mV; and no organic change in the joint on clinical examination. Patients with heart disease, infections, mental illness, and other diseases that might cause imbalance of the joint were excluded.

Ethical approval was obtained before the trial from the Ethics Committee of Shanghai Sixth People’s Hospital (No. 2013-82). All participants gave both verbal and written informed consent.

Experimental design

Patients were randomised into three treatment groups: BTX-A, placebo, and control (n = 10 in each). Differences between groups were assessed at baseline, and none was significant. In the experimental group BTX-A (25 U/ml, 100 U) was injected into three points of the masseter muscles bilaterally. The injection points on each masseter were below the line between the corner of the mouth and earlobe. The areas of masseter muscle when clenched were marked. One of the injection points was in the thickest area of the middle of the muscle, and the other two were located in the line parallel to the mandible (1 cm above and below the first injection point, respectively). The entire treatment consisted of only one session of six injections. In the placebo group isotonic saline was injected into three points of the bilateral masseter muscles in the same way. The control group had no injections.

T-scan analysis

We used an I-Motion occlusal force analyser (version 3.2.0 Analysis System, Shenzhen, China).

All the tests were done between 09 00 and 10 00, with the room temperature at 22-25 °C. Patients were seated upright with the head and neck relaxed, and the Frankfort plane parallel to the floor. The sensor foil was placed on the mandibular occlusal surface. The patient was asked to clench the teeth for 2 seconds and release. Each movement was repeated five times.

Data collection and statistical analysis

Duration of clenching and releasing, the maximum occlusal force, and the distribution of occlusal force were recorded. The asymmetry index of occlusal force (AOF, %) = 100 × (maximum occlusal force of left side – maximum occlusal force of right side)/total maximum occlusal force. All patients enrolled were treated by specialist doctors, and data were collected by another oral surgeon. Data were analysed with the help of SAS 5.0 software (SAS Inc, SAS Institute, NC, USA). Differences in maximum occlusal force, change in maximum occlusal force, and symmetrical distribution analyses among the three treatment groups were compared using the multivariate analysis of variance (ANOVA) and post-hoc Bonferroni test to assess the significance of differences between individual pairs of groups. Levene’s test was done before the ANOVA to test the homogeneity of variance. Because the exact p value was not provided by the post-hoc Bonferroni test, we did a polynomial comparison test to calculate it. The significance of differences in the duration of contact and separation, maximum occlusal force, change in maximum occlusal force, and symmetrical distribution of occlusal force were assessed using Student’s t test.

Results

No patient had any organic changes in the joint on magnetic resonance imaging (MRI), or any systemic disease. There were eight men and two women in each group. In the BTX-A group the mean (range) age was 26 (25–31) years, in the placebo group 28 (25–35) years, and in the control group 31 (28–37) years. All patients were followed-up for 6 months after treatment, and there were no adverse reactions.
Variations

One possible.

Change was significant in the BTX-A group (t = 4.07, p = 0.003) after three months, and decreased after six months, but there was no significant change in relaxing time. There were no significant changes in either the placebo or the control groups (Figs 1-3).

Maximum occlusal force

There was a significant change in maximum occlusal force (F(df = 2) = 1.20, p = 0.32; ANOVA F(df = 2) = 6.21, p = 0.01) in the BTX-A group compared with the other two groups (p<0.05, post-hoc Bonferroni test, no exact p value), and there was no significant difference between the placebo and control groups (post-hoc Bonferroni test, no exact p value) (Table 1). To be specific, the polynomial comparison test showed that there were significant changes between the BTX-A and placebo group and the control group (F(df = 1) = 4.34, p = 0.047), and that between the BTX-A and placebo groups was significant (F(df = 1) = 8.08, p = 0.01). (BTX-A group compared with placebo = t1m = -2.89, p = 0.01; t3m = -2.60, p = 0.02. BTX-A compared with control group = t1m = -3.64, p = 0.002; t3m = -2.87, p = 0.01; t6m = -2.28, p = 0.04.)

Only the BTX-A group showed a significant time-dependent change in the maximum occlusal force, which

Table 1

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Botulinum toxin A</th>
<th>Placebo</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
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<td>One month:</td>
<td></td>
<td></td>
<td></td>
<td>0.002</td>
</tr>
<tr>
<td>Change of maximum bite force (kg)</td>
<td>-41.97 (9.55)*</td>
<td>-7.97 (6.87)</td>
<td>0.94 (6.90)</td>
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<td>Variations in index (%)</td>
<td>0.20 (2.56)</td>
<td>1.90 (3.04)</td>
<td>3.60 (2.51)</td>
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<td>Three months:</td>
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<td></td>
<td>0.006</td>
</tr>
<tr>
<td>Change of maximum bite force (kg)</td>
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<td>-13.33 (6.02)</td>
<td>-8.63 (6.73)</td>
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</tr>
<tr>
<td>Variations in index (%)</td>
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<td>-1.20 (2.44)</td>
<td>-1.40 (2.48)</td>
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<tr>
<td>Six months:</td>
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<td>0.061</td>
</tr>
<tr>
<td>Change of maximum bite force (kg)</td>
<td>-39.79 (13.42)*</td>
<td>-22.53 (7.94)</td>
<td>-3.77 (8.39)</td>
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</tr>
<tr>
<td>Variations in index (%)</td>
<td>-5.00 (3.03)</td>
<td>-3.40 (2.98)</td>
<td>-0.40 (2.36)</td>
<td></td>
</tr>
</tbody>
</table>

The change of maximum bite force (Mean ± SEM, kg):(the row in shadow)

* = P < 0.05; ** = P < 0.01.

Variations in index of bite force distribution symmetry in three groups (Mean ± SEM, %):(the under row).

improvement in both biting time and maximum occlusal force. However, no improvement in the asymmetrical distribution of occlusal force was seen in any of the groups. BTX-A reduces pain through inhibition of activation of the synaptic nerve by blocking the release of acetylcholine from the presynaptic membrane and preventing release of substance P by targeting SNAP-25 to block the release of calcium ions. The maximum occlusal force of the masseter in the intercuspid position was reduced after BTX-A injection, reached its lowest value three months after treatment, and remained lower than the pretreatment value although the difference six months after treatment was not significant. This result is consistent with the pharmacokinetics of BTX-A, and suggests that the masseter muscle has a crucial role in biting and a minor role in opening.

Psychological factors are important in the aetiology of TMD, and so psychological intervention is an intrinsic part of the treatment of TMD. The change in bite force in the placebo and control groups indicates that psychological intervention has played a part in the treatment of TMD and bruxism. Kim et al. stated clearly that TMD are closely related to psychological factors. In research into the treatment of nerve disorders (such as TMD and bruxism), workers have pointed out that psychological intervention can obviously relieve the pain caused by nerve dysfunction. All the existing clinical treatments can therefore be considered to be a combination of that particular treatment and psychological intervention, which affects patients during their treatment.

Our results showed that all three groups had reduced occlusal force at the intercuspid position, though to different extents, but the effect of BTX-A was superior and there were no differences between the placebo and control groups. During treatment, asymmetry of the distribution of occlusal force was reduced in all three groups, but not significantly so. It is likely that the duration treatment was too short to show any difference.

This study was a preliminary investigation into the therapeutic efficacy of injection of BTX-A into the masseter muscle for the treatment of TMD in terms of occlusal force. Whether it provides greater clinical benefit for patients with TMD than other treatments is yet to be shown. Though the computerised occlusion analysis system is both sensitive and accurate, it still has some limitations. Clinical objective and subjective variables should be combined to comprehensively evaluate further the therapeutic efficacy of injection of BTX-A into the masseter muscle for patients with TMD. Whether the efficacy is affected by sex or age also requires further investigation.

We conclude that the occlusal analysis system accurately reflects the characteristics of occlusal force during treatment of TMD. BTX-A has obvious advantages for the treatment of TMD in terms of reducing the occlusal force, but psychological intervention plays an important part in treatment.
Conflict of Interest

We have no conflicts of interest.

Ethics statement/confirmation of patient permission

Ethical approval was obtained from the Medical Ethics Committee of Shanghai Sixth People’s Hospital (NO. 2013-82).

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