Efficiency of BTX-A in the Alleviation of Hemifacial Pain

Mohammed Rhael Ali[1]*, Elham Hazeim Abdulkareem[2]

1. Department of Oral and Maxillofacial Surgery, College of Dentistry, University of Tikrit, Iraq.
2. Department of Oral and Maxillofacial Surgery, College of Dentistry, University of Anbar, Iraq.

Abstract

Temporomandibular disorders (TMD) are common musculoskeletal and neuromuscular conditions that are difficult to manage sometimes and are considered as a significant public health issue. However, several methods have been used for the treatment but no significant effect has been observed. Hence, the present study attempted to evaluate the role of Botulinum Toxin (BTX-A) in reduction of the intensity of pain and muscle contraction.

The study involved 60 patients suffering from severe hemifacial pain. The patients were divided into two groups: Group I was treated with medicine (Myogesic 500 mg, Ibuprofen 500 mg, Paracetamol 500 mg) and Group II with BTX-A. The patients were injected with BTX-A about 2-3 cm above the zygomatic arch, while Group I patients were treated with medications only.

The results showed that the women are more susceptible towards the disease than men, and the highest percentage of TMD patients 36 (55.9%) and 30 (26.7%) were observed within the age range 40-49 years and 30-39 years, respectively. The patients treated with BTX-A revealed a significant ($P<0.01$) relief in pain intensity and reduction in pain attack frequency immediately.

The study showed that the BTX-A seems to be a significant method for the treatment of hemifacial pain. A repeat of injections should not be avoided in the event of recurrence. Well-designed and randomized controlled trial is required in future.

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Introduction

Temporomandibular joint disorders (TMD) is a collection of pathological conditions that causes pain and dysfunction in the jaw joint and masticatory muscles and is considered as a common health problem,[1] often confused with migraine, headaches, and/or facial pain. [2] TMD is a global public health problem affecting 70%–80% of the elderly people between the ages of 20-45, and is seen more oftenly in women.[3] Based on previous surveys, 20–25% of the people exhibit symptoms of TMD globally, while 6-12% of Americans have been seen to suffer from it. About one million new patients are diagnosed yearly with 5% of the population in the Netherlands.[4] The symptom includes pain, clicking of the jaw joints, muscle tension in the jaw region, restricted opening of the jaw, difficulty in chewing, and dizziness.[5] Some other symptoms includes moderate to severe pain in the oro-facial area varying from mild self-limiting to severe with need for seeking on treatment.[6] The most common cause are the occlusal factors, tissue susceptibility, posture defects and stress, effecting long-term tension as a result of inability to adapt the rapid cultural and social changes.

Previously, the diagnoses of muscle disorders were based on clinical examination of the patient [7] and to ascertain the severity of signs and symptoms of TMD, Fonseca´s Anamnestic index (FAI) has been used. FAI is composed of 10 questions and based on the answer of patients, the severity of disease is determined. Any responses with yes gave 10 points, responses of "sometimes" were given 5 points, and responses of No, were given 0 points. The total of points decides the classification of TMD seriousness as absent (0-15 points), mild (20-45 points), moderate (50-65 points), or severe (70-100 points).[8]

Corresponding author:
Mohammed Rhael Ali, Elham Hazeim Abdulkareem, Department of Oral and Maxillofacial Surgery, College of Dentistry, University of Tikrit. Iraq.
E-mail: mhmd_rahil@yahoo.com; den.elham.h@uoanbar.edu.iq

Botulinum toxin (BTX) is a bacterial metalloproteinase created by *Clostridium botulinum.*[9] BTX as a neurotoxin protein prevents the release of the neurotransmitter acetylcholine from presynaptic membrane of the neuromuscular junction and thus, inhibiting muscular contraction and making its action non-functional.[10] BTX was first medically used in 1981 by Alan Scott to inactivate the muscle spasticity in strabismus.[11] BTX provides a reversible effect on muscle with high safety factor, minor side effects [12] and without causing any pain, necrosis or muscle inflammation.[13] Proper doses of BTX reduce muscle tension without weakening the muscle, which creates a good situation for restoring its function.[14] Moreover, it causes no permanent effect within the muscle, and a few years after the injection, the neuromuscular organ returns to its normal functionality. Generally, BTX is commercially used in cosmetics and medical researches.[15] Botulinum toxin Type A (BTX-A) injections have been reported to boost the quality of life of patients sustain from hemifacial spasm HFS.[16] Ernberg et al. concluded that the BTX-A have a positive effect in management of myofascial pain.[17] Additionally, BTX-A have been used in Trigeminal neuralgia (TN) over the last decade and showed a 70% decrease of mean VAS score at the sixth month [18] and Wu et al. have reported that BTX-A treatment has been found safe and efficient against TN.[19] Therefore, the purpose of this study is to assess the efficiency of BTX-A in relieving the hemifacial pain of patients affected with TMD.

Materials and methods

Patient selection

The whole of 60 patients with severe hemifacial pain were admitted to the Oral and Maxillofacial Surgery Clinic at Dental College Hospital/Tikrit University from 01/02/2016 to 01/02/2018, for the treatment of TMD. The study carried out based on the declaration of Helsinki guidelines and with the approval from the regional Ethics Committee which is represented by the Medical Ethics Committee of the Ministry of Health in Iraq. All patients replied a sequence of questions about their history of disease myalgia and its position, joint pain, mouth opening range and kinetics. Clinical examination, both intraoral and extraoral was for each patient with checking of masticatory muscles (tenderness and spasm), occlusal disturbances and headache. Moreover, further investigations were done to exclude patients suffering from other causes of orofacial pain, (like parotid problems, pulpitis and temporal arteritis by orthopantomograph, sialogram, Cone Beam CT Scan, ESR and other blood investigations. The patients were divided into two groups based on their type of medication; 30 patients were treated traditionally by using muscle relaxants and analgesic including: Myogesic 500 mg, Ibuprofen 500 mg, Paracetamol 500 mg twice a day. And the other group of 30 patients were treated by BTX-A injection (50 U/kg body weight).

BTX-A injection technique

Once removing the anesthetic lidocaine hydrochloride cream patches applied 1hour earlier in the temporalis muscle and clean the skin by disinfection, BTX-A injection was administered about 2-3 cm above the zygomatic arch by using a 1ml insulin syringe with 27G needle, as shown in Figure 1. The two injections points with 6 units of BTX-A [Figure 2] was used in each injection point.

Figure 1: BTX-A injection (two red points) in temporalis muscle of patient suffering from TMD.

Figure 2. BTX-A injection.

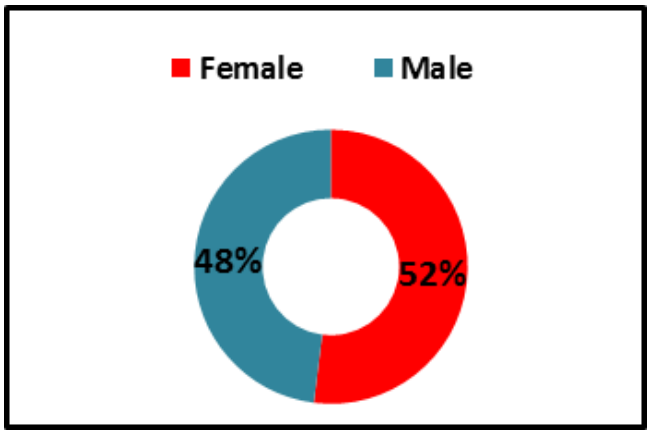

Figure 3: Distribution of the patients.

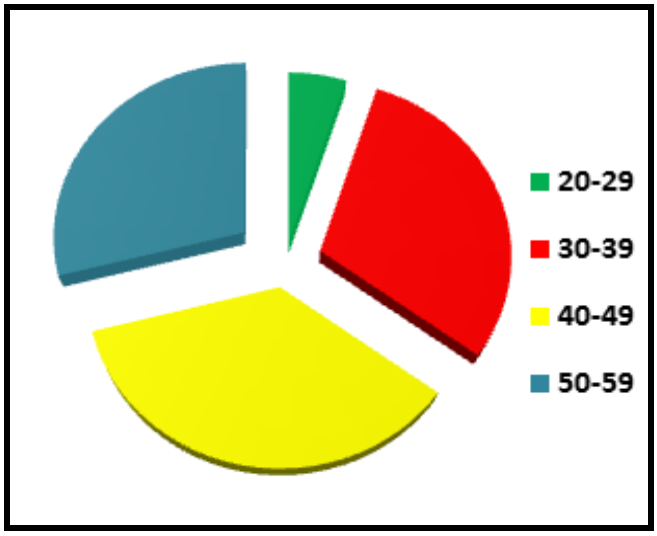

Figure 4. Age of the patients.

The clinical assessment

The efficiency of BTX-A treatment was assessed by the re-examination ofthe patients based on the TMD-P criteria which describe some clinical key features of painful TMD such as mouth opening, the symptom of joint pain, myalgia, arthralgia and headache immediately during the injection time and after 2 weeks and 6 months simultaneously.

Statistical analysis

The statistical analysis of variance (ANOVA test) was performed by Statistical Package (SPSS) system/version 17. Results were expressed as mean ± S.D., and the values were considered to be significant at the level $p<0.05$. The L.S.D. values were compared with values of means difference.

Results

A total of 60 patients were included in the present study. The results confirmed that the women were more frequently affected with TMD (52%). The median age was 37 ± 8.5 ranging from 19-57 years. The majority of TMD patients 36 (55.9%) and 30 (26.7%) were found within the age range of 40-49 years and 30-39 years respectively [Figure 3 and 4]. The results revealed that the patients treated with BTX- A achieved significant relief in pain compared with patients treated with medication only.(Table 1)

	Patients treated by (BTX) Type A (n=30)			Patients treated by medication only (n=30)		
Headache	After injection	2 Weeks	6 months	After injection	2 Weeks	6 months
Open mouth (mm)	12 ± 4.8*	-	-	18 ± 5.2	22 ± 3.6	24 ± 6.3
Clicking of the jaw joint (s)	35 ± 4.6	44 ± 3.0	44 ± 1.5	38 ± 1.6	36 ± 1.4	38 ± 1
Pain in masticatory muscles	20 ± 3.7	7 ± 4.9	5 ± 3	21 ± 5.4	25 ± 4.7	22 ± 6.3
	4 ± 0.5	4 ± 1.3	4 ± 0.6	22 ± 4.5	18 ± 2.8	18 ± 0.9

Table 1. Assessment of patients regarding the types of hemifacial pain treatment.

Discussion

TMD is a significant public health problem, affecting approximately 5-12 % of the population, globally.[20,21] It represents the most common musculoskeletal condition after chronic low back pain which results in pain and disability.[22]

TMD with pain-related can impact the individual's daily activities, psychosocial functioning, and quality of life. Women are about 2 to 4 folds more likely to develop TMD during their lifetime than men.[23,24] Previous study by Buraa and Al-azawi reported that the TMJ disorders were observed more frequently in women than men.[25] Qasim, 2005 confirmed that male to female were nearly equally incidences

with TMD.[26] According to Jitpimolmard et al. (1998),[27] the signs and symptoms of TMD is increased with age and is generally not identified before the age of 50. In another study, the frequency of TMJ disorder was found to be higher in forties and fifties.[25] Such greater frequency of symptoms in female individuals has been observed might be due to the anatomic, biological, and hormonal factors.[28, 29]

The result of this study suggests high efficiency of BTX-A injection in the treatment of patients with TMD compared to the first group, with high significance (static) $P<0.05$. Previously, BTX-A have shown magnificent therapeutic effects with fewer or complete reversible adverse effects. [30] The use of BTX-A appears to remain effective over long-term use of several years (ranging from 4-10 years) and in most cases it doesn't require any increase in dosage.[31] However, it should be considered as a substitute treatment when other conventional method fails to afford satisfactory results[32] and also the side effects are generally transient.[21] The effect of BTX-Aon muscle activity of patients with myofascial pain, recorded alleviation of pain and improvement in psychological indices persisted at re-evaluation of 28 days after the intervention.[33] Furthermore, BTX-A injections lead to reduction in muscle innervation, limits pain in focal dystonia, spasticity and other pain syndromes associated with muscle spasm.[23] In the same manner, Junghans et al. (2007) explained during the study on patient suffering from intense pain arose in the lower part of face and exhibited dyskinesia of caudal mimic musculature that was triggered by specific movements after local injections of BTX-A into the affected region of the patient's face leads to immediate relief of pain following each set of BTX-A injection.[10] Other studies reported that BTX-A injection in the facial pain area significantly relieves pain in trigeminal neuralgia.[15,16] In a study conducted by Sidebottom et al. it has been illustrated that 80% of the patients showed a significant improvement in their symptoms with relieve of arthralgia, and improvement tendency for myalgia, including a significant difference in opening of the mouth 3 months later the first injection.[34]

According to the treatment protocol of the present study, the study is novel and is the first one in Iraq, as it involved the selection of the zygomatic arch for the treatment of TMJ disorders. Though there are several types of treatment involved in treatment of myofascial pain and TMJ disorders, BTX-A represents a safe, effective and economic method. Still, double blinded randomized control clinical trials in case of myofascial pain syndrome in regions other than masticatory muscles shows different results in relation to the effects of verifying beneficial results. [35] The effectiveness of the injected dose influenced by muscle mass and symptom severity, and there is no consensus on the optimum dosage.[36]

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Conclusions

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Declaration of Interest

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