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Evaluation of the Efficacy of Botulinum Toxin Type (A) Injection in Treating Temporomandibular Disorders through Targeted Muscle Intervention

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ABSTRACT

Background: There are numerous therapeutic options available for the treatment of temporomandibular problems that cause persistent orofacial pain and muscular discomfort. When conservative treatment for myofascial TMD fails to provide full recovery, patients may find that botulinum toxin type A (BTX-A) is a preferable substitute. **Objectives:** To evaluate the effectiveness of intramuscular injections of botulinum toxin type A (BTX-A) into the masseter and temporalis muscles in the treatment of myofascial temporomandibular disorders (TMD) and to compare the results with those of a control group that received conservative therapy.

Material & Methods: The Oral and Maxillofacial Medicine and Surgery Center, Shar Teaching Hospital, in Sulaimani, Iraq, conducted a case-control research from August 2024 to June 2025. Using convenient sampling, 40 patients with myogenous temporomandibular disorder (TMD) who met the diagnostic criteria for temporomandibular disorders (DC/TMD) were randomly assigned to one of two equal groups, one of which received intramuscular BTX-A injections and the other conservative treatment. Baseline, two weeks, six weeks, and four months were used to assess the pain score (VAS).

Results: Both groups showed intra-group improvement, but the BTX-A group demonstrated significantly greater pain reduction at all-time points (p<0.05)

Conclusions: BTX-A injections provide superior pain relief in myofascial TMD compared to conservative treatment

Keywords: Botulinum toxin, myofascial pain, temporomandibular disorder, TMJ, muscle injection.

INTRODUCTION

A bilateral synovial joint on either side of the craniomandibular complex, the temporomandibular joint (TMJ) facilitates speech, eating, swallowing, and other reflexive movements like clenching, grinding, and yawning [1, 2]. The temporal bone's glenoid fossa and the mandibular condyle unite to form the ginglymoarthrodial joint known as the TMJ. The second most prevalent musculoskeletal illnesses that cause discomfort and functional impairment are temporomandibular disorders (TMDs), which are a group of conditions that affect the temporomandibular joint (TMJ) or the masticatory muscles [1–4]. There are three categories for TMD. TMD resulting from muscle abnormalities, such as myofascial pain, with or without restrictions in mouth opening, is included in group I. Group II comprises TMD brought on by disc displacement, whether or not there are reductions and restrictions in mouth opening. The third group consists of arthrosis, arthritis, and arthralgia [3]. TMD is twice as frequent in women as in men. Its occurrence peaks between the ages of 20 and 40 [5]. Over half of TMDs present as myofascial pain, which is brought on by parafunctional behaviors such as bruxism or clenching. Although little is known about its genesis, it is most likely complex and involves biological, genetic, psychological, environmental, and anatomical components, including predisposing, triggering, and perpetuating elements [6]. Joint noises, palpable muscle discomfort, joint soreness, or restriction of jaw movement are frequently present in conjunction with the pain, either

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alone or in combination [7]. Pain usually affects the masticatory muscles, preauricular region, or temporomandibular joints, and may limit jaw movement [8]. Warm compresses, behavioral therapy, dental appliances, medications (such as muscle relaxants and anti-inflammatory drugs), and low-level laser therapy are among the various conservative treatments used to manage TMDs [9, 10]. Conventional therapy methods, however, do not always result in total pain alleviation for individuals. In these circumstances, BTX-A intramuscular injections have been suggested in the literature as a substitute therapy because of their capacity to ease pain and relax muscles [11–13].

The purpose of this study was to compare the results with a control group undergoing conservative therapy and assess the effectiveness of injecting botulinum toxin (A) into the masseter and temporalis muscles to treat myofascial pain.

PATIENTS AND METHODS

At the Oral and Maxillofacial Medicine and Surgery Center, Shar Teaching Hospital in Sulaimani, Iraq, a case control research was conducted from August 2024 to June 2025. The study included 40 patients who had been clinically diagnosed with myogenous temporomandibular dysfunction (TMD) according to established diagnostic standards [3]. Two equal groups of 20 patients were randomly selected from among these patients. The first group received conservative treatment, including behavioral instructions. Management involved a soft diet, moist heat application or warm massage, bilateral chewing, avoidance of gum chewing, bruxism, nail biting, and maintenance of proper jaw posture (with the tongue resting on the palate, teeth apart, and jaw relaxed). The second group received intramuscular botulinum toxin type A (BTX-A) injections (Nabota Korya, 150 unit powder). Dosage and injection sites were determined based on individual muscle involvement. Typically, the masseter muscle has 10 units over 6 points (3 on each side), and the temporalis muscle has 40 units over 8 bilateral points. Vials kept at 5°C were reconstituted with 1 mL of room temperature sterile saline to create the BTX-A solution right before injection. Using a visual analog scale (VAS), where 0 denoted no pain and 10 the greatest jaw or facial pain, the degree of pain was measured. Evaluations were documented at baseline (before to intervention), as well as two weeks, six weeks, and four months after therapy. Follow-up evaluations were carried out in accordance with, All patients completed the study; No adverse effects were reported. The Kurdistan Higher Council of Medical Specialties' Ethics Committee gave its approval to the study (number 1870 / Date 13-8-2024). Prior to their inclusion, all individuals gave their informed consent. IBM SPSS Statistics for Windows, Version 27.0 (Armonk, NY: IBM Corp.), was used to perform statistical analyses. Friedman and Mann-Whitney U tests were employed to compare time-based and group-based variables, whereas chi-square tests were used for non-parametric variables. A (p-value) of less than 0.05 was considered statistically significant.

RESULTS

The sample had a mean age of 29.25 ± 12.76 years and included 15 males and 25 females. The two groups' age distribution (p = 0.957) and gender distribution (p = 0.327) did not differ significantly, suggesting that randomization and baseline homogeneity were successful

Table 1: Homogeneity of General Characteristics between the Two Groups

Variable	Conservative treatment	Botox injection	Total	P-value
Gender	Male: 9 (45%)	Male: 6(30%)	15 (37.5%)	0.327
	Female: 11 (55%)	Female: 14 (70%)	25 (62.5%)	
Age (mean ± SD)	31 ± 15.96 years	$27.50 \pm 8.55 \text{ years}$	29.25 ± 12.76	0.957

Pain scores measured at three different time points showed significant improvements in both groups. After receiving a BTX injection, the main result was pain relief, with a general trend for discomfort to get better with time. The Friedman test confirmed a statistically significant reduction in VAS scores over time for both the conservative treatment and BTX-A groups (p < 0.001). The BTX-A group exhibited a rapid decline in pain, with median VAS scores decreasing from 7.0 at baseline to 0.5 at four months. In comparison, the conservative treatment group

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experienced a slower decline, with median VAS dropping from 5.5 to 3.0 over the same period **Table (2)**. As a result, the Botox group's VAS values dramatically dropped, but not the group receiving conservative treatment. **Figure (1)**.

Table 2. Differences in variables in the experimental and conservative groups according to time

Time point	Group	Mean	Sd	Q1	Median	Q3	P-value
Before treatment	conservative treatment	5.70	1.13	5.00	5.50	7.00	0.000
	Botox Injection	6.65	1.09	5.25	7.00	7.00	
2 weeks after	conservative treatment	5.30	1.26	4.00	5.00	6.75	
	Botox Injection	4.20	1.20	3.00	4.50	5.00	
6 weeks after	conservative treatment	4.50	1.40	3.00	5.00	5.00	
	Botox Injection	1.95	1.19	2.00	2.00	2.75	
4 months after	conservative treatment	3.65	1.27	3.00	3.00	5.00	
	Botox Injection	1.00	1.17	0.00	0.50	2.00	

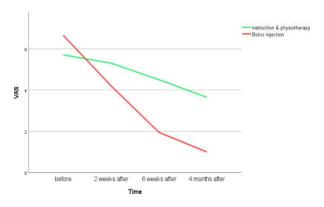


Figure 1: Pain levels on a visual analog scale, Changes in the two groups throughout time.

Mann–Whitney U tests were conducted to evaluate inter-group differences at each time point. These tests revealed statistically significant differences favoring the BTX-A group at all intervals: 2 weeks (p = 0.014), 6 weeks (p = 0.000), and 4 months (p = 0.000), confirming a superior pain-reducing effect of botulinum toxin injections compared to conservative treatment

Table 3: Comparison between conservative treatment and BTX-A Injection

Time point	Mann–Whitney U	P-value
Before treatment	111	0.011
2 weeks after	112	0.014
6 weeks after	31	0.000
4 months after	26	0.000

The results indicate that intramuscular BTX-A injections are significantly more effective in reducing pain intensity than conservative treatment alone, particularly in the early and mid-follow-up periods. While both methods showed

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progressive improvement, the BTX-A group achieved more rapid and sustained pain reduction with no reported complications.

DISCUSSION

The best course of treatment for myofascial pain is still up for debate. Conventional therapy is advised as the initial line of treatment, followed by a multidisciplinary approach. Studies have recently documented the significant therapeutic benefit of BTX in reducing myofascial pain and other related issues observed in TMJ disorders [10, 14]. The benefits of BTX for individuals with TMDs have been the subject of numerous studies and systematic reviews [15–18]. Clostridium botulinum secretes a potent neurotoxin called botulinum toxin (BTX), which has been used. Because it prevents acetylcholine from being released from presynaptic nerve endings, BTX is administered intramuscularly to relax muscles and reduce neurogenic pain. A controversial central impact that by itself lessens chronic pain sensitization is one of the other mechanisms, as is a decreased release of inflammatory mediators. BTX-A has therefore been widely employed in the treatment of TMD due to its analgesic and relaxing qualities as well as its relatively speedy action in addressing poor compliance [19]. Some patients with TMD can benefit from using BTX-A, and there have been no notable adverse effects [20]. According to published research, botulinum toxin injection-related complications are often minor or temporary and can be reduced with the appropriate injection technique. Bruising, hematoma, inframalar area hollowing, weakness in chewing, and loss of fullness are among the often-reported side effects. Myofascial pain injections with botulinum toxin have demonstrated minimal adverse effects, suggesting a safe and efficient therapeutic profile [21].

Conservative methods should be considered as the first line of treatment because of the invasiveness of injections, even though no study has demonstrated the superiority of more conservative treatments like physiotherapy, splint therapy, warm and cold compression, and so on over botulinum injection for TMD symptoms [9]. Individualized jaw self-exercises have been demonstrated to alleviate pain in M-TMD associated with widespread pain [22]. Additionally, it is significantly more helpful to combine jaw exercises with relaxation and counseling [22, 23]. The self-management approach improved functional limitation, increased jaw opening range of motion, and lessened the severity of pain [24]. Research demonstrating the efficacy of a variety of conservative treatment modalities for myofascial pain [25]. According to literature, BTX-A therapy should be started when routine conservative therapy fails [10, 26]. The basic muscles of mastication are the main target of botulinum toxin injection for TMD. Depending on the type of discomfort and physical examination, the injection is usually given in a fixed position approach [10]. BTX-A's impact is correlated with dosage and location [27]. BTX-A has been found in numerous studies to reduce the severity, frequency, and length of recurring episodes, hence providing long-term relief from myofascial TMD. Freund et al. reported on 46 TMD patients who received 150 units of BTX-A to the temporalis and masseter muscles. In their treatment, the temporalis muscles received 25 U and the masseters muscles received 50 U injections. All patients reported significant decreases in both subjective and objective pain levels [14]. In the present study, Doses of BTX-A were based on previous studies [26, 28]. Accordingly, we used 10 units over 6 points (3 on each side) for the masseter muscle, and 40 units over 8 bilateral points for the temporalis muscle. Both sides received injections, regardless of whether the subject had a unilateral or bilateral complaint. However, Ernberg et al. used a total of 50 U of BTX-A injected into 3 standardized sites of the painful masseter muscles [29]. The muscles that are most frequently injected are the masseter and temporalis; this aligns with previous studies [25, 28, 30–32]; however, some also included the lateral pterygoid muscles [10, 33, 34]. Concerning the assessment of pain, in this study, the change in myofascial pain severity was assessed using the visual analogue scale(VAS). Only two studies used behavioral assessments of their patients to assess pain; the majority used a numerical Visual Analog Scale [28, 35]. The main result was pain alleviation following the BTX-A injection, and there was a general trend for pain to get better over the course of four months. Our results demonstrated that, over time, the experimental group's pain level significantly decreased in comparison to the control group. Demonstrating the analgesic effects of BTX-A. However, Short-term improvements, the injection of (BTX-A) decreases the muscle action potential in 14 days, were noted by Kurtoglu et al [28], while other studies [31, 32] evaluated pain score for three months. And some studies evaluated it for 6 months [7, 36]. On the other hand, the study found that TMD patients' pain levels did not significantly improve for three months following the injection of BTX [29].

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CONCLUSION

In patients with TMJ disorders, especially myofascial pain, botulinum toxin type A (BTX-A) injections seem to be beneficial in reducing pain and muscle tension. However, due to the small sample size and brief follow-up, additional long-term studies are advised to confirm sustained safety and efficacy.

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