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Effectiveness of botulinum toxin type an on myofascial pain associated with temporomandibular joint- a prospective observational study

[1]Dr.Raj Kumar Chakraborty, MDS, Ex-PG resident, Department of oral and maxillofacial surgery, I.T.S centre of dental studies & research, Ghaziabad, India.

[2]Dr Amit Gupta, MDS, Reader, Department of oral and maxillofacial surgery, I.T.S centre of dental studies & research, Ghaziabad, India.

[3]Dr Sanjeev Kumar, MDS, FDSRCPS, IBOMS, Professor and Head of department, Department of oral and maxillofacial surgery, SGT University, Budhera, Gurugram, Haryana-122505.

[4]Dr C.S Ram BPT, MSPT [sports], UCCPD, Director-Department of physiotherapy, ITS paramedical College, Ghaziabad, India

[5]Dr Harsha Jain, Ex-Professor, Department of oral and maxillofacial surgery, I.T.S centre of dental studies & research, Ghaziabad, India

[6]Dr Balram Garg, Reader, Department of oral and maxillofacial surgery, I.T.S centre of dental studies & research, Ghaziabad, India.

[7]Dr Nibedita Biswas, Ex-PG resident, Department of orthodontics & Dentofacial orthopedics, KD Dental College and hospital, Mathura, India.

Corresponding Author: Dr Nibedita Biswas, Ex-PG resident, Department of orthodontics & Dentofacial orthopedics, KD Dental College and hospital, Mathura, India.

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Abstract

Objectives: The purpose of this prospective observational study was to evaluate the effectiveness of botulinum Toxin A in reducing myofascial pain in masseter muscle associated with temporomandibular joint with the aid of visual analogue scale, algometry and surface electromyography in patient's refractory to conservative management.

Material and Method: The study was a prospective observational study and was done on 12 participants. Botulinum toxin type A was injected in the bulk of masseter muscle bilaterally, irrespective of the origin of

pain. All the participants showed significant reduction of pain after 14 days up to 6 months of follow up.

Results: There was a statistical significant reduction in myofascial pain which was evident till six months post therapy. This was corroborated by the use of visual analogue scale, electromyography and algometer.

Conclusion: Botulinum toxin type A has a positive result in terms of pain reduction in patients with myofascial pain associated with the temporomandibular joint that was refractory to conservative management. But repeated injection will be required for long term benefits.

Keywords: Algometer, Botulinum toxin types A, Myofascial pain, Surface electromyography, Temporomandibular disorder, Temporomandibular joint.

Introduction

Myofascial pain is attributed to muscular irritation. Facial pain is classified as a deep, somatic, musculoskeletal pain that can be due to protective co-contraction, local muscle soreness, dystonia or centrally mediated myalgia [1].

Myofascial pain of masseter muscle associated with temporomandibular joint (TMJ) is a frequent cause of visit to pain clinics and maxillofacial surgeons. The pain may be referred to other parts of face and neck. It may become a chronic disorder, making it pathology in itself. When such pain involves the masticatory musclesit is classified under temporomandibulardis orders (TMDs).Most cases of TMDs appear to be mild and self-limiting. But, some end up being a cause of chronic pain. Clinically there is a trigger point, exquisitely tender, with/without a radiating tendency usually to adjacent muscles [2].

Subjective signs can be recorded on Visual Analogue scale[VAS]. VAS is a reproducible score over a short period of time with no gender discrimination [3].

Objective signs, on the other hand, can be recorded with a pressure algometer. Algometry scores over manual palpation in terms of repeatability. Visscher et al.[4] found significant differences in tenderness on palpation and algometry. Wieckiewicz W et al. [5] concluded that pressure algometer has 74.5% diagnostic accuracy in determining symptoms of TMDs.

Surface electromyography (SEMG) can be used to assess muscle contraction [6, 7]. As a muscle in pain will have different electrical activity than an aymptomatic muscle during contraction, SEMG records the electrical activity and assists in follow up once the therapy has been initiated. But Klasser GD et al.[8] found that SEMG to be of limited value in diagnosis and follow up of TMD. However it is more useful in a controlled research setting.

Treatment of myofascial pain associated with temporomandibular joint can be conservative like behavioral modification, medication and occlusal splints [9]. These modalities may provide some/temporary/complete relief. On the other hand, botulinum toxin A injection [Btx-a] can be used to provide relaxation to the involved muscles by chemical denervation [10] when subject's response is refractory to conservative management.

The aim of this study was to evaluate, for six months, the effectiveness of botulinum toxin A in reducing myofascial pain of the masseter muscle associated with temporomandibular joint with the aid of VAS, algometry and SEMG in patients refractory to conservative management.

Materials and methods

The study was conducted in the Department of Oral and Maxillofacial surgery, I.T.S. Centre for Dental Studies and Research, Muradnagar, Ghaziabad between December 2017 and January 2019.Ethical committee approval was vide reference number ITS CDSR/IIEC/2017-20/OS/04. A total of 12 patients were included in this prospective observational study.

The inclusion criteria were defined as subjects:

1. Aged 15-50 years.

2. With American Society of Anesthesiology (ASA) physical status classification of 1 and 2.

3. Diagnosed with myofascial Pain caused by hyperactivity of masticatory muscles, parafunctional movements and hypermobility.

4. Who have been previously treated conservatively with no relief.

The exclusion Criteria were defined as subjects:

1. Aged <15 years and >50 years.

2. With history of allergic reaction to Btx-a.

3. Who are pregnant or are nursing mothers.

4. Who are Immunocompromised or have trigeminal neuralgia.

5. With prior treatment with Btx-a or currently undergoing therapy.

6. with radiographic signs of temporomandibular joint arthrosis, rheumatoid arthritis and previously open joint surgery or with neuromuscular junction disorders such as myestheniagravis, lambert-eat on syndromeand orofacial tardive dyskinesia.

7. Consuming medications causing neuromuscular transmission interactions, anti-depressants or anti-inflammatory drugs.

A complete case history was taken in a standardized proforma. Routine investigations were done and informed consent was taken from all patients enrolled in the study. Sample size for this study was calculated in the following manner [11]:

The standard normal deviate for $\alpha = Z_\alpha = 1.960$

The standard normal deviate for $\beta = Z_\beta = 0.842$

Correlation r = 0.724

$C = 0.5 * \ln [(1+r)/(1-r)] = 0.916$

Total sample size = $N = [(Z_\alpha+Z_\beta)/C]^2 + 3 = 12$.

Subjective evaluation was done with VAS, pre and post therapy [Fig.1][6].Objective evaluation was done with SEMG [Aleron 201,records and Medicare systems pvt. ltd, panchkula, Haryana] [fig 2] to assess muscle contraction ,pre and post therapy, in clenched state.

Analogue pressure algometer [ALGO-AN-01, Orchid scientific and innovative India pvt. ltd, Nashik, Maharashtra] [fig 3] to analyze muscle tenderness in masseter muscle extra orally, pre and post therapy.

For reconstituting the Btx -a 100 unit vial [siax by medytox, south korea] was diluted with 4 mL of 0.9% of unpreserved sterile saline according to manufacturer recommendations.1 mL tuberculin syringe with a 0.30-gauge half-inch needle was used for the procedure. Patch test [intradermal] with test dose of 2.5 u [0.1 mL] was done on volar surface of right forearm to check for Btx-a allergy. Following a waiting time of 30 minutes, the muscles were painted. The bulk of the masseter muscle was held at its anterior and posterior borders. A point was marked on the muscle bulk irrespective of the tender points. The needle was pushed into the muscle till it hit bone, retracted 0.5 cm and then injected. Btx-a was injected in dose of 25 units per muscle [fig 4]. The needle was retracted all the way up to the subcutaneous layer as the toxin was deposited in all three heads of masseter-superficial, middle and deep. This was done bilaterally. All the measurements and injections were administered by a single operator.

Patients were called on the following day to check for any injection related complications like pain, swelling, signs of infection. All the subjective and objective readings were taken on the baseline [pre-operative] , 7th , 14th day[post-operative] and after 6 months.

Statistical Analysis

The statistical analysis was done by statistical software SPSS version 20.0. Normality of data was tested by shapiro-wilk test. In the descriptive statistics mean, standard deviation, median were calculated. Spearman's

co-relation was performed between two methods of objective measurement. The significant difference of the parameters between different time intervals was tested by wilcoxon signed rank test. The level of significance and confidence interval were 5% and 95% respectively.

Results

6 male and 6 female subjects were included. The statistical analysis yielded the following results [table1]-

A] The SEMG shows highly significant [P<0.01] values 7th post op day onwards till sixth month indicating change in muscle activity. Only on the 6th month the left SEMG showed no significant difference implicating return of muscle tone .

B] The VAS shows highly significant [P<0.01] values 7th post op day onwards till sixth month indicating reduction in muscle pain for upto six months. In the left masseter the pain was significantly reduced even though the muscle tone had normalized.

C] The algometer readings also show highly significant [P<0.01] values 7th post op day onwards till sixth month indicating objective change in muscle tenderness.

D] A few readings on the SEMG show reduced values on SEMG preoperatively. This correlated clinically with the subjects inability to clench due to pain.

Discussion

Temporomandibular disorders include a Heterogenous group of musculoskeletal and neuromuscular conditions involving the temporomandibular joint[TMJ] , the surrounding musculature and bony components. Muscular irritation causes myofascial pain which may or may not be associated with TMJ. This can become chronic in nature and debilitating if not intervened [12].The Research Diagnostic Criteria for Temporomandibular disorders [RDC/TMD] was in introduced in 1992 to classify TMD's. It has,hence, standardized the diagnostic criteria of TMD's including myofascial pain. This has been validated for research and clinical use[13].

According to RDC/TMD, myofascial pain falls under the physical diagnosis axis (muscle disorder), as the first group disorder. It is subdivided as myofascial pain with or without limited mouth opening. Manfredini et al.[14] found that myofascial pain with or without mouth opening limitation was the commonest diagnosis in TMD patient population.

Uncertainty is the term that describes the pathophysiology behind myofascial pain associated with TMJ. Multiple theories have been advocated in literature based on neurology, psychology and muscle imbalance. The most accepted theory is based on the fact that myofascial pain originates from hyperactive muscles that develop trigger points [MTRPs].These trigger points evoke a pain that gets centrally converged. These trigger points result from direct trauma, strain, overuse or repetitive micro trauma. The cause of the MTRP's is the increased acetylcholine [ach] release in to neuromuscular junction. This eventually causes a hypoxia-reperfusion injury that leads to bradyk in in release in muscle and other agents that sensitize notice ptors and cause pain in MTRPs [15, 16].

The modalities to arrest, stabilize or reverse this muscle hyperactivity include conservative therapies viz patient education [7], hot fermentation, oral medications, physical isometric exercises and splint therapy [11].The more invasive therapies include dry needling and other direct muscle interventions vizinjection of local anesthesia and Btx-A[12].

Btx-a (neurotoxin) isolated from Clostridium Botulinum, is being used to treat conditions of muscle hyperactivity like blepharo spasms, strabismus, cervical dystonia, limb spasticity, bladder incontinence and in facial aesthetics [17]. Btx-a stops the release of Ach from the neuromuscular junction that starts and maintains MTRPs.

It also decreases the pain by acting on the nociceptive nerve endings[4].Amitgupta et al.[18]and Kurtuglo C et al.[19] concluded that Btx-a injection decreases muscle activity in 14 days and reverts back to baseline in 8 weeks. Our study shows significant pain relief by the 7th day itself that continued to improve over the period of six months. But Ernberg et al. [20] in their randomized, placebo controlled study concluded that there was no clinically significant effectiveness of Btx-a in treatment of myofascial pain. Also Chen YW et al. [21] concluded that no concens us could be reached regarding therapeutic benefits of Btx-a and suggested future rigorous trials.

Manual palpation is gold standard to evaluate MTRPs. But has the disadvantage of inability to quantitatively assess the result and non repeatability [5].The pressure algometer can overcome these shortcomings. Macdonald et al. [19] concluded that algometer is reliable in evaluating MTRP and also can be used to confirm diagnosis/quantify irritability and evaluate therapeutic effectiveness. Chesterton LS et al.[23] concluded that in hands of trained people algometer is highly reliable. Stuginski-Barbosa J et al. [24] found a weak co-relation between pain intensity and pain pressure threshold. Linde LD et al. [25] tested and proved that a co-relation exists between rate of pressure application and pain pressure threshold. In our study, we found that with adequate practice the operator could reproduce similar pattern of applying pressure proving it to be a good tool to monitor the progress of treatment. On the other hand, .Szyszka-Sommerfeld L et al. [26] assessed diagnostic value of algometer and concluded that it can't be used as a solitary tool neither for diagnosis nor for screening purpose .We too feel the same and conclude that it should be used as an adjunct for screening, diagnosing and evaluating progress of the treatment. Hence, our study included SEMG along with algometer to enhance the credibility of our readings.

Every muscle in human body has an electrical activity that is proportional to the level of muscle activity. Electromyogram records this activity. SEMG is easy to use, noninvasive, and safe and has patient compliance. Its shortcomings include poor selectivity and records artifacts [27]. We used SEMG due to patient acceptance and resource constraints. SEMG records the electrical activity of the tender muscle and can assist in follow up after Btx-a therapy has been initiated. Our study indicates initial decrease followed by an increase in muscle activity as the pain reduced over a period of six months, thus evaluating the effectiveness of therapy. But in literature it is still not recommended for diagnosis or screening of TMD. Problems associated with clinical application limits its usage, one of which is standardization of SEMG recordings [28]**.** In our study two patients could not perform isometric contractions initially due to the myofascial pain itself recording low activity preoperatively with a little increase in the activity after 7 days. But later on, the activity recorded was eventually less with a gradual increase up to 6 month. This is an essential finding and hence we do not recommend SEMG as a single modality to evaluate the effectiveness to Btx-a therapy but only as an adjunct. This corroborates with conclusions by Suvinen TI et al [29], Gary D Klasser et al [8], Suvinen TI et al [6].

Thus, myofascial pain is a condition with multifactorial etiology. Btx-a is being used since past two to three decades in alleviating pain associated with TMJ. Literature suggests that masseter and temporalis muscle should be treated as a couple and Btx-a should be injected in both the muscles. We hypothesized that that if we inject the masseter muscle alone with Btx-a then pain associated with TMJ can be reduced. This is based on the explanation that Btx-a has a direct effect on the muscle via relaxation and on TMJ by reducing inflammation.It also has an

indirect effect on the TMJ, wherein, by reducing the load on TMJ the joint is spared which consequently reduces the pain [18,30]. In most of our cases with masseter muscle pain only, this held to be true. But in two cases with masseter and temporalis muscle involvement only pain of masseter muscle was alleviated. Thus we can infer that the effect may be localized to the area/muscle of involvement only. Pain reduction was quantified subjectively by pressure algometer and VAS respectively. Both VAS and pressure algometer have shown reliability in their interpretation of clinical pain. On the other hand, SEMG readings have shown changes in muscles contraction reflecting the initial decrease followed by increase in activity as pain in the muscle subsided. These findings help us conclude that Btx-a is an effective treatment in myofascialpain involving the masseter muscle. But, we do acknowledge that the sample size is small and the time of evaluation was 6 months only. Evaluation of the long term effectiveness will require more prospective randomized trials with large number of cases followed up for a longer period of time. We would also like to co-relate the parameters used for pain measurement. Thus, we conclude that Btx-a injection in masseter muscle for myofascial pain associated with TMJ is an effective but temporary measure .We further suggest that investigating and treating the underlying cause when the patient is asymptomatic will yield better results for the patient. This is in conjunction with the recent systematic review [31].

Conclusion

Our study concludes that Btx-a alleviates masseter muscle myofascialpain associated with TMJ. We also conclude that it is a temporary minimally invasive measure to alleviate pain and improve quality of life in patient's refractory to other conservative therapies. The injection in bulk of the muscle irrespective of trigger point can reduce pain. Hence, we advocate its inclusion in a clinician's repertoire. The limitations of the present study was its small sample size and the short time frame in which the effects were evaluated. Also the co-relation of SEMG and algometer readings warrants investigation. Thus, further studies with larger sample size and longer period of evaluation are required to enlighten the void.

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Legend Tables

Table 1: Comparison of parameters Mean ± S.d (Median) between different time intervals:

Right EMG	Pre-op		7th day		14th day		6th month	
Mean ± S.d (Median)	438.17±354.78 (349.50)		399.17±318.373 (248.50)		306.42±189.566 (224.50)		747.25±301.879 (689.50)	
P-value	0.099 a(NS)	0.005 b(**)		0.002 c(**)		0.028 d(*)		0.004 e(**)
Left EMG	Pre-op		7th day		14th day		6th month	
Mean ± S.d (Median)	7.23 ± 1123.104 (430.50)		403.67 ± 306.469 (267.00)		276.92 ± 154.729 (217)		762.17 ±348.461 (624)	
P-value	0.060a(NS)	0.002 b(**)		0.002 c(**)		0.006 d(**)		0.071 e (NS)
Right VAS	Pre-op		7th day		14th day		6th month	
Mean ± S.d (Median)	2.92 ± 1.311 (2.50)		2.92 ± 1.311 (2.50)		5.92 ± 1.676 (5.50)		10 ± 0.000 (10.00)	
P-value	1.000 a(NS)	0.002 b(**)		0.002 c(**)		0.002 d(**)		0.002 e(**)

Left VAS	Pre-op	7th day	14th day	6th month	
Mean ± S.d (Median)	2.92 ± 1.311 (2.50)	3.08 ± 1.505 (2.50)	6.17 ± 1.697 (6.00)	10.00 ± 0.000 (10.00)	
P-value	0.157 a (NS)	0.002 b(**)	0.002 c(**)	0.002 d(**)	0.002 e (**)
Right Algo	Pre-op	7th day	14th day	6th month	
Mean ± S.d (Median)	2.92 ± 2.466 (2.00)	3.58 ± 2.610 (3.00)	5.67 ± 1.614 (5.00)	10.67 ± 1.775 (11.00)	
P-value	0.023 a(*)	0.004 b(**)	0.002 c(**)	0.003 d(**)	0.002 e(**)
Left Algo	Pre-op	7th day	14th day	6th month	
Mean ± S.d (Median)	3.92 ± 2.234 (3.50)	4.25 ± 2.221 (4.00)	5.67 ± 1.923 (5.50)	11.25 ± 1.815 (11.50)	
P-value	0.046*	0.017*	0.002**	0.007**	0.002**

Legend

a -Pre-op vs 7th Day; b -7th day vs 14th day; c -14th day vs 6th month; d - Pre-op vs 14th day; e - Pre-op vs 6th month

NS - Not significant p > 0.05 ; ** - Highly significant p<0.01 ; *- Significant p<0.05, EMG-Electromyograph, Vas-Visual Analogue Scale, Algo-Algometer

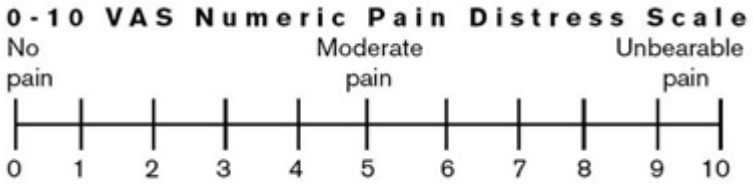

Figure 1

Figure 2

Figure 3

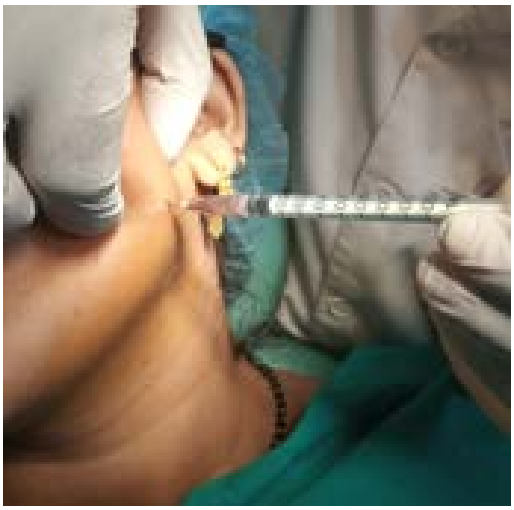

Figure 4