

COMPARATIVE STUDY BETWEEN BOTULINUM TOXIN A AND PLATELET RICH PLASMA IN THE TREATMENT OF MYOFASCIAL PAIN WITHIN MASSETER MUSCLE (A RANDOMIZED CLINICAL TRIAL)

Amira M. Aglan BDS^{1*}, Mostafa M. El Dibany PhD²,
Marwa G. Noureldin PhD³, Hoda M. Abdel-Naby PhD⁴

ABSTRACT

INTRODUCTION: Masticatory myofascial trigger points (TrPs) are considered from the main sources of pain of non-dental origin in orofacial area. Intramuscular injections are believed to be the standard therapy of myofascial TrPs. Botulinum toxin A (BTX-A) may relieve myofascial pain through inhibition of α -motor nerve endings and blocking nociceptor transduction. Platelet rich plasma (PRP) injection into the masseter muscle is a new treatment which aids in the relief of pain owing to its analgesic and anti-inflammatory effect.

OBJECTIVE: To evaluate and compare the effectiveness of BTX-A and PRP injections on muscle activity, visual analogue scale (VAS) for pain, pressure pain intensity (PPI) and jaw functional limitation scale (JFLS) in patients having myofascial TrPs within the masseter muscle.

MATERIALS AND METHODS: Twenty six patients suffering from myofascial TrPs within the masseter muscle were selected and randomized into two groups: Group 1 (n=13) received BTX-A injection and group 2 (n=13) received PRP injection. Muscle activity during rest and during function were determined after 6 months, VAS for pain, PPI and JFLS scores were determined at the 1, 3 and 6-months follow-up visits.

RESULTS: There was significant improvement seen in both groups at the 1-month follow-up. BTX group exhibited significant changes regarding VAS, PPI and JFLS scores at the 3-months follow-up, while PRP group showed significant changes regarding VAS and JFLS only. At the 6-months follow-up, both groups' patients relapsed to initial records.

CONCLUSION: This study showed that BTX has superior results when compared to PRP in alleviation of myofascial pain. However, patients need to repeat BTX injection every 6 months to restore its effect.

KEYWORDS: Myofascial pain, trigger points, botulinum toxin type A, platelet rich plasma.

RUNNING TITLE: Comparing BTX and PRP in myofascial pain treatment.

1-B.D.S Faculty of Dentistry Alexandria University

2-Professor of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University, Alexandria, Egypt

3-Lecturer of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University, Alexandria, Egypt

4-Lecturer of Physical Medicine, Rheumatology and Rehabilitation Physical Medicine Department, Faculty of Medicine, Alexandria University, Alexandria, Egypt

**Corresponding author:*

amiraaglan2404@gmail.com

INTRODUCTION

Myofascial pain is a neuromuscular disease affecting muscles and fascia causing confined pain and tenderness in the muscle; it is usually accompanied by continuous localized pain in different body parts including back, shoulder, head, and orofacial region (1,2). Active trigger points (TrPs) present with myofascial pain syndrome stimulate localized muscle pain (3).

Myofascial TrPs arise as local contractions of skeletal muscles characterized by being hard, painful, and tender when palpated (3,4). TrPs cause pain when compressed which can be transmitted to the surrounding area (5,6). The area of TrP has poor blood supply and inflammatory environment (4,7,8).

Pain can be reflected to distant areas even though it usually occurs over the TrPs (6,9). The clinical manifestations in these painful areas appear as cramps, weakness, rigidity and expansion of muscle fibers along with muscular restraint and limitations in the extent of TMJ movement (6,10).

Pain of the masticatory muscles and TMJ, tinnitus, torticollis and headache are among clinical manifestations of head and neck myofascial pain (2,9,10). Persistent facial pain present in the orofacial area is mainly caused by masticatory myofascial pain (11). Muscles of mastication are a main cause of orofacial pain (12).

Several noninvasive procedures have been used to alleviate pain caused by TrPs including

massage, spraying and stretching, physical therapy, transcutaneous electrical stimulation (TENS), muscle relaxants and tricyclic antidepressants (1,7,9). Invasive procedures comprise dry needling and injections with corticosteroids, local anesthetic, platelet rich plasma (PRP) and botulinum toxin (BTX) (1,6,8).

Botulinum toxin type A (BTX-A) which is a toxin produced by bacteria, prevents releasing of acetylcholine at neuromuscular junctions. It was employed in the treatment of dysfunctions related to muscles of orofacial area including dystonia, hypertrophy of masseter and temporalis muscles and TMJ disorders as it causes muscle paralysis (13).

Growth factors take part in regeneration and development of muscles as they induce myoblasts' proliferation and differentiation. PRP is a concentration of growth factors that supply activated platelets upon injection therefore it helps decreasing inflammation, relieving pain, enhancing function and inducing muscle healing (8).

The null hypothesis of this study was no significant difference will be found in treatment of myofascial TrPs in the masseter muscle between the group injected with BTX-A and the one injected with PRP.

This study aimed to evaluate and compare the effectiveness of BTX-A and PRP injections on muscle activity, visual analogue scale (VAS) for pain, pressure pain intensity (PPI) and jaw functional limitation scale (JFLS) in patients having myofascial TrPs within the masseter muscle.

MATERIALS AND METHODS

The study was performed as a randomized clinical trial with a 1:1 allocation ratio that was carried out upon approval of the Research Ethics Committee at the Faculty of Dentistry, Alexandria University, on 19/9/2021. Ethics Committee No: 0289-09/2021. Prior to the procedure, all patients signed an informed consent form at Alexandria University's Faculty of Dentistry's Oral and Maxillofacial Surgery Department, to ensure and confirm their understanding of the procedure's outcome and the risks associated with this intervention.

Patients

The study was conducted on 26 patients suffering from pain resulting from myofascial TrP in the masseter muscle. Patients were enlisted from the outpatient Clinic of Alexandria Main University Hospital. This trial was designed and reported according to CONSORT guidelines (14).

Sample randomization

This study was a randomized clinical trial with a 1:1 allocation ratio done by simple randomization using computer generated random numbers. A total of 26 patients were divided into 2 equal groups:

Group I: Consisting of 13 patients received Botulinum Toxin type A injection (BTX-A).

Group II: Consisting of 13 patients received platelet rich plasma injection (PRP).

Inclusion criteria (15)

Pain transmitted from TrPs comprised in the masseter muscle and diffused in the mouth, face or TMJ.

Masseter muscle having myofascial pain as described by the American Academy of Orofacial Pain and the Research Diagnostic Criteria for TMD (RDC/TMD)(16,17).

Persistent symptoms for not less than 3 months.

Visual analogue scale (VAS) recording not less than 3 points on a 10 points VAS.

Exclusion criteria (15,18)

Pregnant and lactating women.

Joint and muscle diseases.

Neurological disorders.

Bleeding disorders.

Patients who underwent any therapy in orofacial muscle or TMJ before.

Any patient with preexisting TMD.

Materials

Botulinum Toxin type A (Allergan plc, Dublin, Ireland).

The active substance is botulinum toxin type A from clostridium botulinum. Botox is presented as a thin white powder that may be difficult to see on the bottom of a transparent glass vial. Prior to injection, the product must be dissolved in sterile unpreserved normal saline (0.9% sodium chloride for injection). The vial contains 100 Allergan Units of botulinum toxin type A.

Insulin syringe (Sung Shim Medical Co., Ltd., Bucheon, Korea).

Single-use insulin syringe with sterile interior 1ml/cc, 30G x 8mm.

A 0.9% Saline (El Fath for drugs and cosmetics industry (FIPCO), Borg El Arab City, Alexandria, Egypt).

Anticoagulant vacutainer tube (Hebei Xinle Sci&Tech Co., Ltd, Hebei, China).

3.2% sodium citrate, 1.8 ml blood collection glass tube.

Plain vacutainer tube (El Dawlia Import & Export, El-Azbakia, Cairo, Egypt).

5 ml plain glass tube.

Neuropack S1 EMG/EP measuring system (Nihon Kohden CO., Tokyo, Japan).

Electric Centrifuge model 80-1 / 4000 RPM / 6* 20 ml (Wincom Company Ltd. China).

Adjustable speed and time: two rotary switches to control speed and time, the speed range is 0-4000 rotation per minute The time range is 0-60min.

20 ml X 6 rotors: the tubes need to be inserted into the machine symmetrically, it is not allowed to operate the machine asymmetrically. If the Sample is singular, a tube of clean water is added to achieve symmetrical operation.

Methods

Pre-operative assessment

Clinical examination

Patients were assessed by taking full personal, dental and medical histories.

The following criteria were used to detect the presence of active TrPs:

Single or multiple palpable taut bands in a skeletal muscle.

Hyperirritable point within the taut band.

Snapping palpation of the taut band producing local twitch response.

Pain triggered by TrPs having the same symptoms of habitual pain (12).

Rigorous clinical examination was done to determine the following:

Masseter muscle activity assessed by electromyography (EMG)

The masseter muscle activity was assessed using EMG. While recording, patients were seated in a comfortable position without headrest aligned parallel to the floor according to Frankfort horizontal plane.

After skin disinfection with alcohol, a conductive gel was used to increase the conductivity of the electrode-skin interface. The active recording electrode and the reference electrode were positioned on the motor point of the masseter muscle and angle of the jaw respectively. A ground electrode was positioned on the forearm.

Electromyography readings were reported in a resting mandibular position, then the patient kept clenching for 5 seconds. EMG was registered on maximum tooth clenching, then EMG was registered during gum chewing at right followed by the left side. The electromyographic amplitude records (mV) were evaluated preoperatively and 6 months post-injection.

Pain according to visual analogue scale (VAS)(15)

The average pain level at rest and while chewing was assessed using 10- point visual analogue scale (VAS), with 0 designating pain absence, whereas 10 signifying high pain degree.

Pain according to pressure pain intensity (PPI)(19)

Pressure pain intensity (PPI) records were gained by pressing the thumb vertically on the skin covering the muscle comprising the TrP till whitening of the nail bed.

PPI scores were recorded on a scale from 0 to 3 with 0 designating pain absence and 3 signifying high pain degree.

Jaw movements according to jaw functional limitation scale (JFLS)(20)

The jaw functional limitation scale (JFLS) measures three general limitations which are mastication, jaw mobility, and emotional and verbal expression. The scale is made up of eight questions through which patients answer each question on a scale from 0 to 10 to show the degree of limitation.

Operative procedures

The most tender area in the masseter muscle was determined by manual palpation.

Trigger points injection sites were marked by a white pencil eyeliner after skin disinfection with 70% ethyl alcohol where the number of injection points was determined according to the number of trigger points detected in each patient

Group I (Figure 1)

Patients were injected with BTX.

The drug used was onabotulinumtoxinA Allergan 100 units.

Hundred IU BTX were dissolved into 2 ml of sodium chloride 9 mg/ml (0.9%) to prepare a clear BTX solution.

Using a 21-gauge needle, the 2 ml saline was inserted into the vial and then the vial was tilted at a 45° angle. The present vacuum demonstrated the intact sterility of the vial which was then liberated by detaching the syringe and allowing air to flow into the vial. The BTX and saline were gently mixed.

A single dose of 10 U BTX-A was administered in each TrP using a (1-ml, 30-gauge needle) insulin syringe.

The Allergan vial was kept in the refrigerator at 2°C–8°C up to 15 days after its dissolution without losing its effectiveness or any sign of microbiological contamination.

Group II (Figure 2)

Patients in this group were injected with PRP.

Venous blood of volume about 20 ml was collected from the patients and transmitted into four anticoagulant (3.2% Sodium citrate) vacutainer tubes.

A double spin technique was used to produce PRP.

The first spin was done at 1,800 rpm for 15 minutes to obtain 3 layers (red blood cells, PRP and platelet poor plasma).

The platelet poor plasma and PRP layer were transmitted into another plain tube to undergo a second spin for 10 minutes at 3,500 rpm to produce around 2-4 ml of pure PRP.

Each TrP received 0.5 ml PRP using a (1-ml, 30-gauge needle) insulin syringe. (Figure 3)

Post-operative care and medication

Postoperatively, all patients were directed to:

Stick to a soft diet and let their masticatory muscles rest for 7 days.

Use Paracetamol (Paracetamol 500mg tablet, Sedico Company, Giza, Egypt) as the optimal analgesic only when needed.

Stay in a vertical position for 6 hours.

Avoid intense physical exercise or heat exposure for 24 hours.

Avoid manipulation of the injected area after treatment for a minimum of 6 hours.

Apply ice packs on the injected area.

Follow up

Postoperative clinical evaluation

Patients were recalled after 1, 3 and 6 months post-injection. Pain according to VAS and PPI and jaw movements were measured in the same manner as in the pre-operative phase.

Electromyography recordings were taken 6 months post-injection. The difference between pre and post recordings was evaluated to detect muscle action.

Statistical analysis

Normality was checked using Shapiro Wilk test and Q-Q plots. Normally distributed variables were (age, and amplitude) while non-normally distributed variables were (VAS, PPI, and JFLS). All variables were presented using mean, median, standard deviation and inter quartile range except ordinal variable (PPI) was presented using median, inter quartile range, minimum, and maximum in addition to scores frequencies.

Comparisons between groups were done using parametric independent t test and non-parametric Mann Whitney U test according to data's normality. For within group comparisons, non-parametric; Friedman test was done followed by post hoc test with Bonferroni correction, if results were significant. Changes before and after treatment regarding EMG readings were analyzed using parametric paired t test and non-parametric Wilcoxon Sign rank. Significance level was set at p value 0.05. IBM SPSS version 23 was used to perform data analysis.



Figure (1): Photograph (A) showing recording masseter muscle activity by EMG. Photograph (B) showing marking landmarks by a white pencil eyeliner. Photograph (C) showing BTX injection into the masseter muscle.



Figure (2): Photograph (A) showing recording masseter muscle activity by EMG. Photograph (B) showing marking landmarks by a white pencil eyeliner. Photograph (C) showing PRP injection into the masseter muscle.

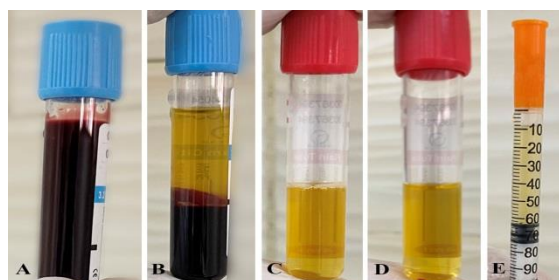


Figure (3): Photograph showing PRP preparation. A) Whole blood. B) RBC buffy coat supernatant plasma. C) only supernatant plasma layer was removed. D) Upper 2/3 rd (PPP) was discarded & lower 1/3 rd (PRP) was resuspended. E) Final product (PRP).

RESULTS

Twenty six patients allocated into two groups (group I received BTX and group II received PRP) were enrolled in this study, none were excluded or lost during follow-up. The mean age of group I was 30.69 years with a range (20 to 40), and the mean age of group II was 28.46 years with a range (20 to 38). No difference was detected between groups regarding the mean age and gender ($P > .05$).

Patients were divided into two groups, all suffering from pain resulting from myofascial TrP in the masseter muscle selected from the outpatient Clinic of Alexandria Main University Hospital and operated in Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University.

Postoperative results

Clinical data

Masseter muscle activity evaluated using EMG

The EMG readings of the masseter muscle were taken preoperatively and 6 months post injection. (Figure 4)

Preoperatively, the amplitude records of the masseter muscles ranged between 0.5–1.5 mV. In the BTX group (I), the means of the EMG amplitude records (mV) of right masseter and left masseter were 1.02 ± 0.30 and 0.92 ± 0.16 , before the intervention and became 0.76 ± 0.68 and 0.78 ± 0.46 , respectively, after 6 months. This denotes a decrease in the means of the EMG amplitude records of the masseter muscles following injection, but this decrease was statistically insignificant ($P > 0.05$).

The means of the EMG amplitude records (mV) of right masseter and left masseter muscles in the PRP group (II) were 0.96 ± 0.24 and 0.87 ± 0.18 at the beginning of the study and became 0.93 ± 0.38 and 0.89 ± 0.31 , respectively, after 6 months. Hence, no significant difference was detected in PRP group.

After six months, EMG readings of the masseter muscles in both groups related to the pre-injection recordings. No significant difference was detected between both groups. The p value was evaluated using independent t test. (Table 1)

Pain according to visual analogue scale (VAS)

Measurements of VAS records were taken preoperatively at the day of injection and at 1, 3 and 6 months follow-ups. At the 1-month follow-up, significant improvement in the VAS pain records compared to initial records was obtained in both groups. VAS pain scores did not significantly differ between groups with ($P = 0.075$) where the

mean VAS record of the BTX group was 0.92, compared with 1.85 in the PRP group.

After 3-months, VAS pain records for both groups showed significant improvement with regard to the initial records, and the VAS record of BTX group was significantly less than that of PRP group ($P = 0.012$) where the mean VAS of the BTX group was 1.62, compared with 4.69 in PRP group.

At 6-months, no significant difference was detected in both groups in comparison to initial records ($P > 0.05$). Yet the BTX group exhibited significant improvement regarding VAS pain scores when compared to PRP group with ($P = 0.002$). (Table 2) (Figure 5)

Pain according to pressure pain intensity (PPI)
PPI values improved significantly in both groups after 1 month when compared to initial records, but there wasn't any significant difference between both groups ($P = 0.623$).

After 3-months, significant improvement in PPI records compared to initial records was detected in BTX group ($P < .0001$) while PRP group showed no significant improvement ($P = 1$). PPI values of BTX group was significantly less than values of PRP group ($P = 0.007$).

After 6-months, no significant improvement was detected in both groups nor between them. (Table 3)

Jaw movements according to jaw functional limitation scale (JFLS)

At 1-month, both groups exhibited significant improvement in JFLS values compared to initial values ($P < 0.0001$). On comparing both groups no significant difference was detected with ($P = 0.104$).

At 3-months, both groups continued to show significant improvement with respect to baseline values but BTX group was significantly lower than PRP group with ($P = 0.022$).

At 6-months, no statistically significant improvement was found in JFLS values of both groups compared to baseline values. On comparing the two groups no significant difference was detected with ($P = 0.150$).

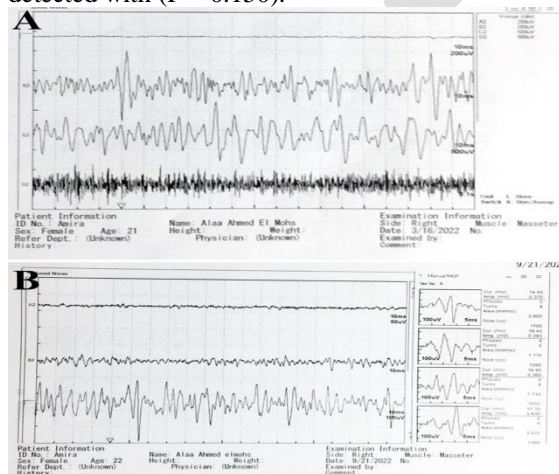


Figure (4): (A) showing EMG results preoperatively. (B) showing EMG results after 6 months

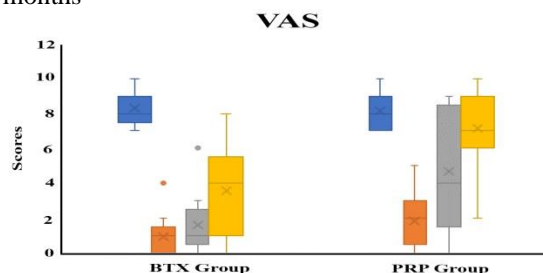


Figure (5): Comparison of the VAS scores between BTX group and PRP group.

Table (1): Comparison of amplitude (mV) between BTX group and PRP group preoperative and 6 months postoperative.

		BTX Group (n=13)		PRP Group (n=13)		P value
		Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Right	Preoperative	1.02 (0.30)	1.00 (0.50)	0.96 (0.24)	0.90 (0.32)	0.550
	6 months	0.76 (0.68)	0.50 (0.70)	0.93 (0.38)	0.90 (0.50)	0.438
	P value	0.178		0.705		
Left	Preoperative	0.92 (0.16)	0.90 (0.25)	0.87 (0.18)	0.90 (0.25)	0.531
	6 months	0.78 (0.46)	0.60 (0.49)	0.89 (0.31)	0.80 (0.50)	0.484
	P value	0.286		0.794		
Overall	Preoperative	0.97 (0.24)	0.90 (0.40)	0.92 (0.21)	0.90 (0.30)	0.401
	6 months	0.77 (0.57)	0.60 (0.55)	0.91 (0.34)	0.85 (0.45)	0.287
	P value	0.079		0.938		

Table (2): Comparison of VAS between BTX group and PRP group at different time intervals.

	BTX Group (n=13)		PRP Group (n=13)		P value
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Preoperative	8.31 (1.03)	8.00 (2.00)	8.15 (0.99)	8.00 (2.00)	0.728
1 month	0.92 (1.19)	1.00 (2.00)	1.85 (1.46)	2.00 (3.00)	0.075
3 months	1.62 (1.66)	1.00 (2.00)	4.69 (3.33)	4.00 (7.00)	0.012*
6 months	3.54 (2.67)	4.00 (5.00)	7.15 (2.12)	7.00 (3.00)	0.002*
P value	<0.0001*		<0.0001*		
Pairwise comparisons	P1<0.0001*, P2<0.0001*, P3=0.166, P4=1.00, P5=0.007*, P6=0.290		P1<0.0001*, P2=0.009*, P3=1.00, P4=0.201, P5<0.0001*, P6=0.290		

*Statistically significant difference at $p \text{ value} \leq 0.05$.
 P1: comparison between preoperative and 1 month,
 P2: comparison between preoperative and 3 months,
 P3: comparison between preoperative and 6 months,
 P4: comparison between 1 month and 3 months,
 P5: comparison between 1 month and 6 months,
 P6: comparison between 3 months and 6 months.

Table (3): Comparison of pressure pain intensity (PPI) scores between BTX group and PRP group at different time intervals.

	BTX Group (n=13)		PRP Group (n=13)		P value
	Median (IQR)	Min - Max	Median (IQR)	Min - Max	
Preoperative	2.00 (2.00)	1.00 - 3.00	2.00 (2.00)	1.00 - 3.00	0.623
1 month	0.00 (1.00)	0.00 - 2.00	1.00 (1.00)	0.00 - 2.00	0.051
3 months	1.00 (1.00)	0.00 - 3.00	2.00 (2.00)	0.00 - 3.00	0.007*
6 months	1.00 (2.00)	0.00 - 3.00	2.00 (2.00)	0.00 - 3.00	0.124
P value	<0.0001*		<0.0001*		
Pairwise comparisons	P1<0.0001*, P2<0.0001*, P3=0.059, P4=1.00, P5=0.201, P6=1.00		P1=0.002*, P2=1.00, P3=1.00, P4=0.037*, P5=0.037*, P6=1.00		

*Statistically significant difference at $p \text{ value} \leq 0.05$.
 P1: comparison between preoperative and 1 month,
 P2: comparison between preoperative and 3 months,
 P3: comparison between preoperative and 6 months,
 P4: comparison between 1 month and 3 months,
 P5: comparison between 1 month and 6 months,
 P6: comparison between 3 months and 6 months.

DISCUSSION

This study compares the effectiveness of BTX-A and PRP in management of masticatory myofascial pain due to lack of evidence comparing effectiveness of both.

Patients selected in this study were of both genders ranging between 20 to 40 years which is considered the most affected age group agreeing with many researchers as Laskin and Block who stated that MPDS is most likely to appear in 20 to 40 years age group. The mean age in our study was 29.6 years old. In our study, MPDS was more

common in females than males with the ratio 6:1 similar to reports by Carlsson et al. and Butler et al which stated that MPDS has more frequent effect among females than males with a ratio varying from 3:1 to 5:1 (18). This higher prevalence may be as a result of lower pain threshold, higher anxiety, and higher rate of psychological stresses in women (21).

In our study, a small dose (10-30) U of BTX was injected in trigger points of the masseter muscle only of group I patients. It was mentioned in literature that the effect of little BTX injection in both masseter and temporalis muscles is greater than injecting masseter muscle solely with larger dose of BTX (22). Grover et al. (23) found that the best effect of BTX with the least possible dose can be achieved by injecting both masseter and temporalis muscles.

In 2021, a systematic review of clinical trials, concerning injections of masticatory muscles as a treatment modality for myofascial pain, mentioned that masseter muscle is the most frequently injected masticatory muscle by needling procedures (65%), followed by the temporalis muscle (27%) (24).

In our study, we found that BTX had an optimal results regarding pain relief and jaw functions till the 3 months follow-up. Various researches reported that the outcome of a single BTX injection subsides in nearly four months post injection according to the manufacturer’s recommendations (25).

Platelet rich plasma injection into the masseter muscle is a new treatment which aids in the relief of pain owing to the analgesic and anti-inflammatory effect of the released protease activated receptor 4 peptides from alpha granule in the platelets (26,27). In addition to being a cost-effective and easily prepared treatment, PRP has a low chance of infection or any adverse effect since it is an autogenous substance produced from the patient’s own blood (28). Several researchers supported using PRP injection as treatment modality, Borrione et al. (29) used PRP in muscle healing and Quarteiro et al. (30) applied it in management of rats’ muscle injury. Hancı et al. (31) used PRP in management of temporomandibular disorders while Knop et al. (32) treated osteoarthritis using PRP. Covey et al. (33) and Sheryp et al. (34) employed PRP to cure planter fasciitis pain.

In this study, group II patients received 0.5 ml PRP in each trigger point of the masseter muscle and was found to be effective for 3 months regarding pain relief. According to previous studies, the best results were obtained 2–10 days after injection as platelets have a life span of 7–10 days. A remarkable improvement in muscle activity after injecting PRP in muscles of rats from the third till the fourteenth day was detected by Hammond et

al. Researchers suggested that patients should repeat injection of masseter muscles with PRP till fulfilling the desired outcome (8).

In our study we used double spinning technique for PRP preparation similar to the technique used by Reurink et al. (35) to prepare PRP in management of acute muscle injury, it was chosen to concentrate platelets in order to elevate the effectiveness of growth factors (36). Filardo et al. (37) reported that single spinning technique increase platelet concentration 1 to 3 times that of standard levels while the increase 4 to 8 times is achieved by double-spinning. However, Wang-Saegusa et al adopted single spinning technique in PRP production in view of the fact that single spinning technique produces the same outcome in an easier way and less preparation time (38). Filardo et al. (37) found no significant difference between single and double spinning techniques with respect to the efficiency of PRP.

The primary outcome of interest was studying the effect of BTX-A and PRP injections on EMG activity of masseter muscles in patients having myofascial pain. In the present study, all patients recorded high amplitude records preoperatively denoting muscle hyperactivity, which is in accordance with Shetty et al. (39) who explained that muscle hyperactivity is related to bruxism and myofascial pain. In our study, the EMG amplitude records of the masseter muscles in the BTX-A group (group I) showed no significant decrease at the 6-months follow-up. This agrees with results obtained from the study done by Fathy et al. (22) who found that EMG recordings relapsed to initial values after 6 months of BTX injection. The EMG amplitude readings of PRP group (group II) relapsed to the pre-injection recordings.

All patients in both groups recorded high baseline VAS scores ranged from 7 to 10. In our study, BTX-A group (group I) showed significant reduction in VAS results at the 1 and 3 months post-injection follow-ups. After 6 months, VAS results showed insignificant decrease. These results can be explained by the fact that outcome of a single BTX injection subsides in nearly four months post injection according to the manufacturer's recommendations (25).

Our results showed that PRP injection (group II) significantly reduced the mean VAS score after 1 month post-injection. At their 3-months visit, patients demonstrated variable increase in the VAS scores, yet the VAS results showed significant reduction. After 6 months, all VAS scores relapsed to the baseline records. These results are in agreement with Morad et al. (18) who detected marked results of PRP till the 3-months follow-up only. NiteckaBuchta et al. (8) discovered that PRP administration had noticeable effect in reducing pain over masseter muscle for a short period (up to 14 days), this is inconsistent with our

study results that showed significant improvement in pain records till 3 months postoperatively. This may be due to different protocols of PRP preparation and different administration methods.

Preoperatively all patients showed variable PPI scores. Patients of both groups recorded decreased PPI values at their 1-month appointment. While patients in the BTX-A group (group I) sustained decreased PPI scores at the 3-months visit before increasing again after 6 months, patients in the PRP group (group II) had elevated PPI scores at the 3 and 6-months follow-ups. Matching results were seen in several studies that used different techniques in management of MPDS (15,18,40).

Chronic pain has a negative effect on masticatory function; hence pain alleviation strongly reduces functional limitation. JFLS was used to determine the masticatory function as a dependent outcome. Patients suffering from pain in muscles of mastication might have deficient masticatory function as stated by Shimada et al. (41). In our study, JFLS results improved significantly in BTX-A group (group I) at 1, 3 post-injection follow-ups only with insignificant improvement detected after 6 months. These results agree with previous studies which reported that the best treatment outcomes were achieved after 1–4 weeks till 3–6 months relying on each patient (42). This disagrees with results attained by Yurttutan et al. (43) who encountered a significant reduction in JFLS scores after 6 months of BTX administration in patients having MPDS. The JFLS scores in the PRP group (group II) showed significant improvement till the 3 months follow-up.

This research may have some limitations. Initially, it lacked a control group that wasn't given any treatment or given dry needling. The study included relatively small number of participants. Finally, EMG assessment was done at the 6 months follow-up only.

It was concluded that marked decrease in pain intensity was seen in both treatment methods used in the present study 1 month postoperatively with significant increase in PPI values of PRP group after 3 months, the decrease in VAS scores was more prominent in patients who received BTX injection than in patients who received PRP injection after 3 and 6 months. This difference may be due to the transient effectiveness of PRP.

CONCLUSION

From the results of this study we can conclude that: BTX injection had better outcomes when compared to PRP injection in management of myofascial pain regarding pain according to VAS and PPI, and jaw functions.

Patients need to repeat BTX injection every 6 months to restore its effect.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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