Botulinum Toxin, Lidocaine, and Dry-Needling Injections in Patients with Myofascial Pain and Headaches

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0886-9634/2701-000$05.00/0, THE JOURNAL OF CRANIOMANDIBULAR PRACTICE,

Manuscript received April 22, 2008; revised manuscript received September 16, 2008; accepted September 17, 2008

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ABSTRACT: Trigger point injections with different solutions have been studied mainly with regard to the management of myofascial pain (MFP) patient management. However, few studies have analyzed their effect in a chronic headache population with associated MFP. The purpose of this study was to assess if trigger point injections using botulinum toxin, lidocaine, and dry-needling injections for the management of local pain and associated headache management. Forty-five (45) myofascial pain patients with headaches that could be reproduced by activating at least one trigger point, were randomly assigned into one of the three groups: G1, dry-needling, G2, 0.25% lidocaine, at 0.25% and G3 botulinum toxin and were assessed during a 12 week period. Levels of pain intensity, frequency and duration, local post-injection sensitivity, obtainment time and duration of relief, and the use of rescue medication were evaluated. Statistically, all the groups showed favorable results for the evaluated requisites ($p \leq 0.05$), except for the use of rescue medication and local post injection sensitivity (G3 showed better results). Considering its reduced cost, lidocaine could be adopted as a substance of choice, and botulinum toxin should be reserved for refractory cases, in which the expected effects could not be achieved, and the use of a more expensive therapy would be mandatory.

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Myofascial pain (MFP) is a neuromuscular disorder characterized by localized muscle tenderness and pain, and frequently associated with persistent regional pain such as back pain, shoulder pain, tension type headaches, and orofacial pain. Parafunctional habits and poor postures, unfavorable physical, social, behavioral, and emotional conditions can act as initiating or perpetuating factors, activating the trigger points, thus causing pain and dysfunction.[1]

A trigger point (TrP) is defined as a localized deep tenderness in a taut band of skeletal muscle that is responsible for the pain in the zone of reference, and if treated, the resultant pain will be resolved.[2]

The points may be active or latent.[2,3] Palpating the active TrP with sustained deep single finger pressure on the taut band will elicit an alteration in the pain (intensification or reduction) in the zone of reference, or cause the pain to radiate towards the zone of reference. This can occur immediately or be delayed for a few seconds. The pattern of referral is both reproducible and consistent with patterns of other patients with similar TrPs. This enables a clinician to use the zone of reference as a guide to locate the TrP for purposes of treatment.[4-5]

Treatment of MFP can range from simple cases with transient single muscle syndromes to complex cases involving multiple muscles and many interrelating contributing factors, including the presence of fibromyalgia (FBM). Many authors have found success in treatment of MFP using a wide variety of techniques such as exercise, trigger point injections, vapocoolant spray and stretch, TENS, biofeedback, posture correction, tricyclic antidepressants, muscle relaxant and other medications, and addressing perpetuating factors. However, the difficulty in management lies in the critical need to match the level of complexity of the management program with the complexity of the patient. Failure to address the entire problem including all involved muscles, concomitant diagnoses, and contributing factors may lead to failure to resolve the pain and perpetuation of the pain.[1,3,6-10]

Trigger point injections, procaine, lidocaine, mepivacaine, saline solution, corticosteroids, and botulinum toxin may be used in various concentrations and associations. Dry-needling also presents satisfactory results, but with more post-injection sensitivity.[2-5,7,13-28,46]

Local anesthetics act by blocking nervous conduction by competition for calcium uptake, preventing sodium ions from leaving, depolarizing and propagating the action potential, while dry-needling acts by mechanically rupturing the trigger points.[7]

Botulinum toxin type A has been used to treat patients that are refractory to conventional therapy. It presents favorable results that last from two to six months and has fewer undesirable effects.[4,16,23,27-34,47-49]

Some patients may require a new application in a period of less than six months, and this could be explained because the patient's immunological system is stimulated, and generally the toxin is neutralized by the antibodies. For these cases, association with physical therapy would minimize the need for reinjections.[26,30]

It is believed that the toxin's link with the motor plate membrane nerve endings blocks the release of acetylcholine, thus preventing muscular contraction and reducing the pain associated with tension.[4,16,23,26-34]

Some authors suggest that botulinum toxin could be indicated for the treatment of patients with tension type headaches, migraine with and without aura, and those refractory to conventional treatment. For migraine cases, the bilateral application of toxin in pre-established sites should be preferred, even in patients that specifically have unilateral headaches. Application that accompanies the pain trajectory should be avoided, since it could produce a cosmetic effect and the pain could occur on the opposite side. In general, the success indexes are higher than 80% of the cases.[11-13]

In cases of migraine with aura, applications tend to diminish the headache, but the aura tends to remain unaltered. Response to the use of triptans frequently improves after treatment with the toxin, but patients that present with allodynia tend to continue to have an unfavorable response to them.[11-13]

Broadly speaking, the results have shown to be progressive after repeated injections. It may be necessary to increase the doses, have association between applications in pre-established locations and to follow the trajectory of pain.[11-13]

Botulinum toxin may also be effective in the treatment of chronic daily headache. In this case, a scheme that associates injections in pre-established points and points that accompany the pain trajectory is very interesting. This same scheme may also be adopted in cases of post-traumatic headache.[11-13]

The doses range between 50 and 100 units. Injection of small doses in multiple sites reduces the occurrence of side effects and effectively controls headache. In general, 2.5 to 5U are applied at each point. Intra-muscular injections cause less discomfort than intradermal injections. An interval of three months between applications should be observed to prevent the development of antibodies.[11-13]

Although there are various forms of treatment for headache patients, it is valid to remember that their success is directly related to adequate diagnoses. Treatment directed to the place and not to the origin of the pain will result in failure and the clinical condition can consequently becoming chronic.[3,7-10,35]

Myofascial pain is presented as an entity that deserves attention and study, to enable the treatment techniques to be improved.

It becomes necessary to study different substances, doses and techniques for treating trigger points, since there is no consensus in literature, mainly with regard to the orofacial region.

The majority of studies that used botulinum toxin type A for treating patients with tension and migraine type headaches used the frontal and temporal region as the injection point. As it is necessary to direct the treatment to the origin of the pain, it would be necessary to locate the points associated with the reproduction of the headache complaint in each patient individually, and then proceed to the the injections.

Materials and Methods

The objective of this study was to compare the use of two different substances for trigger point injections to dry-needling, in order to alleviate local and referred pain to the head (headache complaint). Outcome measures

will include levels of pain intensity, frequency and duration, local post-injection sensitivity, obtainment time and duration of relief and the need to use analgesics to control headaches. The study was conducted at the Araraquara School of Dentistry - UNESP, where 45 patients (40 females and five males), between the ages of 18 and 65 years, with myofascial pain and headache, were selected in accordance with the following criteria:

- Inclusion: moderate to severe headache present for at least six months; at least one uni- or bilateral trigger point in the orofacial (masseter, temporalis) or cervical region (occiput, trapezius) sensitive to palpation, responsible for setting off the headache;
- Exclusion: arterial hypertension, diabetes, hypoglycemia, blood dyscrasias, tumors, lupus, fibromyalgia, rheumatoid arthritis, allergy to the solutions and use of anti-coagulants.

Among those selected, 25% presented with tension type headache (TTH), 15% with migraine, and 60% mixed headache (TTH with episodic migraine attacks).

Only one patient abandoned treatment due to a back problem. All patients signed a Term of Free and Informed Consent, approved by the UNESP Research Ethics Committee. The patients were submitted to anamnesis and a physical exam in order to confirm the diagnosis of myofascial pain and headache reproduced by means of palpating the trigger point, and to enable the data obtained during the treatment to be compared. Headache diagnosis and classification were made in accordance with the criteria of the International Headache Society (IHS).[45]

The patients were divided into three groups by random draw: Group 1: dry-needling; Group 2: lidocaine at 0.25%, without vasoconstrictor[19,20]; and Group 3: botulinum toxin 25 or 50U.

Palpation of a hypersensitive muscle fiber bundle or nodule of harder than normal consistency is the physical finding most often associated with trigger points. Localization of a trigger point is based on the clinician's sense of touch, assisted by patients' expressions of pain and by visual and palpable observations of local twitch response observations. This palpation will elicit pain over the palpated muscle and/or cause the pain to radiate toward the zone of reference, in addition to a twitch response. The commonly encountered locations of trigger points and their pain reference zones are consistent. The trigger points were located using digital palpation (1.5 Kg), and the clinical examiner was calibrated using a pressure algometer.[2]

Once a trigger point has been located and the overlying skin has been cleansed with alcohol 70, the clinician isolates this point by pinching it between his/her fingers and then inserts the needle 1-2 cm away from the trigger point, so that the needle may be advanced into the trigger point at an acute angle of 30 degrees to the skin.

Before advancing the needle into the trigger point, the plunger should be withdrawn to ensure that the needle is not within a blood vessel. A small amount (0.2 ml) of substance should be injected once. The needle is then withdrawn to the level of the subcutaneous tissue, and then redirected upwards, downwards, sideways and medially, repeating the needling and injection process in each direction until the local twitch response is no longer elicited or resisting muscle tautness is no longer perceived. In the present study, the injections were given with disposable syringes (BD) 13x4.5, 26G 1/2, five ml and BD Precision Glide 0.45x1326G 1/2 needles (BD, Franklin Lakes, NJ).[27] Each patient was injected in one to three trigger points, selected in accordance with headache reproduction at the time of physical exam. In this study, dry-needling was used as the group control, so that only the two substances used in this study would be compared: lidocaine 0.25% and botulinum toxin, since mechanical disruption of the point was performed in the three groups.

Results Assessment

1. *The modified Symptom Severity Index (SSI),[52] is composed of three subscales of pain*: frequency, intensity, duration. Each sub-scale may vary on a scale of 28 points on VAS. Each sub-scale has an *x*/28 relation, where *x* would be the number of points marked by the patient. The index was calculated by adding every subscale and dividing the final result by three.

2. *Palpation of the trigger point and reproduction of the chief complaint (headache)*: the calibrated examiner palpated neck and masticatory muscles with a pressure of 1.5 kg.

3. *Pain diary*: A daily assessment of the intensity of the pain and the need for using rescue medication. During the experimental period, these patients were allowed to use rescue medication for headache, prescribed at the first treatment session (ibuprofen - 200 mg). The patient could ingest the medication three to four times per day, without exceeding the maximum dose of 2,400 mg/day).

4. *Pain questionnaire*: the time it took to alleviate the local sensitivity at the injection site, as well as the time elapsed between the injections and to alleviate the headache.

To avoid the patient's cooperation from having influence on the results, no instructions were given to subjects about any other therapeutic modality, including self-care management, counseling, or home physical therapy.

During follow-ups, patients were asked if they were using any treatment modality for pain control, other than

the rescue medication (ibuprofen 200 mg). The patients were assessed before, ten minutes after, one week, four weeks, and 12 weeks after the injections.

Results

By means of the Analysis of Variance with repeated measurements, it was observed that the groups did not present significant difference of behavior (p=0.5599). There were also no significant differences for the baseline means, one, four, and 12 weeks (p=0.2125).

The 1-week time period differed from the the 4-week time period (p=0.0555, with significantly lower values), yet did not differ from the 12-week period (p=0.0993). There were no differences in the 4-week time period from the 12-week period (p=0.9713) (**Table 1**).

It was possible to note a significant improvement from the time before to 10 minutes, with this improvement being maintained in the other periods assessed for points 1, 2, and 3 in the three groups studied (McNemar Test). When the studied groups were compared, however, there was no significant difference in any of the injected points and in any of the times assessed (Fischer's Test) (**Tables 2** and **3**).

Ingestion of rescue medication (number of 200 mg ibuprofen pills ingested) (**Table 4**)

Based on the nonparametric Friedman test, it was observed that:

- Group 1 (DN) presented significant alteration throughout the assessments made (p=0.034). The 1-week time period differs significantly from the 4-week time period (p<0.05), presenting significantly lower values. The other comparisons show no significant differences.
- Group 2 (L) presented significant alteration throughout the assessments made (p=0.001). The 12-week time period differs significantly from the other time periods (1-week: p<0.05 and 4-week: p<0.05), presenting significantly higher values.
- Group 3 (TB) presented significant alteration throughout the assessments made (p=0.014). The 1-week time period differs significantly from the 12-week (p<0.05), presenting significantly lower values.

Time for relief of local sensitivity and headache after injection application. (**Tables 5** and **6**)

Using the Analysis of Variance (ANOVA) with repeated measurements, it was observed that the groups did not present significant difference of behavior (p=0.8373). The groups presented significant difference in the means before and at ten minutes (p=0.0420). The botulinum toxin and dry-needling groups presented no significant differences (p=0.8892) and differed from the lidocaine group that presented higher means. There was a significant decrease for the four groups from the time before to the ten minute time period (p>0.001).

Discussion

Several studies have shown favorable results regarding the use of injections at trigger points for the management of myofascial pain signs and symptoms and headache.[3-5,9-13,31,32,36-42] Although the association between these disorders appears to be clear, treatments directed only at alleviating or controling the head pain have shown discouraging results in a chronic population. The lack of diagnostic criteria and lack of knowledge of the techniques would appear to contribute greatly. The choice of doses and therapeutic schemes would appear to be directly related to the occurrence of these findings. Non-individualization of techniques, as a result of pre-established methodologies, lack of follow-up of cases, the complexity of cases and the high response to placebo treatments

Table 1
Means and Standard Deviations for Symptom Serverity Index (SSI)

Group	Baseline	1-week	4-week	12-week
DN	0.52 (0.09)	0.34 (0.08)	0.42 (0.08)	0.36 (0.17)
L	0.60 (0.21)	0.40 (0.09)	0.46 (0.19)	0.46 (0.24)
BT	0.44 (0.19)	0.33 (0.22)	0.38 (0.14)	0.44 (0.19)

DN: dry-needling; L: lidocaine; BT: botulinum toxin

Table 2
Intensity of Pain on Palpation (0-3) at the Injected Trigger Points at the Different Times Assessed

	Point 1						Point 2						Point 3					
	DN		L		BT		DN		L		BT		DN		L		BT	
	0-1	2-3	0-1	2-3	0-1	2-3	0-1	2-3	0-1	2-3	0-1	2-3	0-1	2-3	0-1	2-3	0-1	2-3
Before	1	14	0	15	1	14	0	14	0	15	1	14	0	8	1	12	0	11
10 min	12	3	10	5	14	1	9	5	13	2	12	3	5	3	11	2	9	2
1-week	14	1	13	2	12	3	12	2	11	4	9	6	6	2	11	2	11	0
4-week	13	2	13	2	14	1	12	2	12	3	13	2	8	0	10	3	11	0
12-week	12	3	11	4	14	1	13	1	13	2	15	0	8	0	11	2	10	1

DN: dry needing; L: lidocaine; BT: botulinum toxin

are important factors to be considered when discussing the results.[9-13]

In 2004, Kamanli, et al.[22] compared TrP injections with botulinum toxin type A (BTX-A) to dry-needling and lidocaine injection in 29 patients with myofascial pain. Clinical assessment included: cervical range of motion, TrP pain pressure threshold (PPT), pain scores (PS), visual analog scales (VAS) for pain, fatigue, and work disability were evaluated at baseline and at the end of the fourth week. Three groups were evaluated: lidocaine 0.5%, 10-20 IU of BTX-A and dry-needling. Patients were instructed to continue their home exercise programs. Pain pressure thresholds and PS significantly improved in all three groups. In the lidocaine group, PPT values were significantly higher than in the dry-needling group, and PS were significantly lower than in both the BTX-A and dry-needling groups. Visual analog scores significantly decreased in the lidocaine and BTX-A injection groups and did not significantly change in the dry-needling group.

Kamanli, et al.[22] concluded that trigger point injection is more practical and rapid, since it causes fewer disturbances than dry-needling and is more cost effective than BTX-A injection, and seems to be the treatment of choice in MPS. On the other hand, BTX-A could be selectively used in MPS patients resistant to conventional treatments.

In the current study, 45 patients as opposed to 29 were evaluated. Also, a very specific subgroup (patients with myofascial pain with associated headaches) was evaluated, and the aim of the study was to compare the different techniques in the management of headaches. The length of the current study was 12 weeks as opposed to four weeks. Statistically, all the substances tested showed favorable results, with particularities that will be discussed later. We also used a different concentrarion of lidocaine (0.25%) and different units of BTX (25-50 IU).

As expected, the studied groups showed no variation in behavior for the Symptom Severity Index (SSI), with significant reduction of symptom frequency, intensity and duration. However, it was possible to perceive a trend towards a reduction in the effects attained during the course of the period assessed, showing that although the results expected are satisfactory, they have a short duration. This also emphasizes the importance of combined therapies for controlling the other possible related etiologic factors,[1,3,6-8,10,14,17,35,43] such as sleep quality, poor postural habits, oral parafunctions and dietary issues.

Although the literature describes a relief duration period of approximately three months with regard to botulinum toxin use, some patients experienced a shorter period of relief with recurrence of the clinical condition before the expected period.

The possible reasons for recurrence of symptoms include persistence of etiologic factors and presence of muscular lesions.

Specifically with regard to this study, standardization of the number of points to be injected in a minimum of one and a maximum of three points brought about some limitations, mainly for cases in which the number of points related to the reproduction of the complaint was higher than the one permitted.

During the initial physical exam, the points that were mostly able to reproduce patients' headache complaints

Table 3
Reproduction of Main Complaint (Yes/No) at the Injected Trigger Points at the Different Times Assessed

	Point 1						Point 2						Point 3					
	DN		L		BT		DN		L		BT		DN		L		BT	
	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
Before	15	0	15	0	15	0	14	0	15	0	14	1	8	0	13	0	8	0
10 min	4	11	8	7	6	9	7	7	5	10	7	8	4	4	5	8	2	6
1-week	2	13	3	12	4	11	1	13	3	12	4	11	1	7	4	9	3	5
4-week	3	12	3	12	3	12	3	11	5	10	3	12	0	8	2	11	2	6
12-week	2	13	5	10	4	11	1	13	4	11	2	13	0	8	4	9	1	7

DN: dry-needing; L: lidocaine; BT: botulinum toxin; Y: yes; N: no

were selected. Nevertheless, in accordance with the clinical and scientific findings established, it is known that there are latent and satellite points and points of irradiation convergence from distinct points to a certain region.

Probably, individualization with regard to the number of points injected and to the interval between reinjection may be the key to controlling chronic cases, since the technique of rupturing the nodules and the most suitable concentrations have already been previously established.[1,2,5,8,15,17-22,24,27,30,43,44]

The reduction in the number of headache episodes may possibly be explained by the reduction observed in the ingestion of rescue medication (ibuprofen). All the studied groups showed less need to use this drug to alleviate the symptoms. There was a significant drop not only related to the number of pills ingested (dose), but also in the frequency of ingestion, a relevant factor in controlling the etiology of headaches, when analyzing the role medications play in rebound headaches.

Although statistical analysis done using the Kruskal-Wallis test revealed an absence of statistical significance, especially as a result of the great variation in the values found for the standard deviations, at the 12-week period, it was possible to note a trend toward a reduction in the ingestion of rescue medication for Group 3 (botulinum toxin). Probably, an analysis done at eight weeks would show this trend towards reduction in a more compelling manner, indicating a more lasting effect with regard to relief from symptoms for the patients treated with botulinum toxin.

Table 4
Means, Standard Deviations, and p Values for the Number of Ibuprofen Pills Ingested

Group	1-week	4-week	12-week
DN	5.53 (8.35)	16.66 (26.22)	32.93 (61.17)
L	5.86 (6.23)	23.53 (26.92)	35.28 (45.20)
BT	9.86 (17.80)	6.86 (7.25)	15.53 (21.93)
p-value between groups*	0.6284	0.1141	0.0553

DN: dry-needling; L: lidocaine; BT: botulinum toxin
*Absence of statistical significance for 1, 4, and 12 weeks (Kruskal-Wallis test)

Table 5
Means, Standard Deviations, and p Values for the Number of Days on Which the Injected Points Remained Painful

Group	Number of days
DN	2.53 (1.76)
L	1.73 (1.27)
BT	0.80 (1.08)
p-value between groups*	0.0011

DN: dry-needling; L: lidocaine; BT: botulinum toxin
*Statistically significant difference for all the groups (Kruskal-Wallis test). Group 3 (BT) presented significantly lower values than those of group 1 (DN) (Dunn test, $p<0.5$). The other comparisons do not present significant differences.

Table 6
Means and Standard Deviations for the Intensity of Headache Before Application and Ten Minutes After Injection Was Applied

Group	Before	Ten min. after
DN	5.26 (2.21)	2.40 (2.22)
L	7.13 (2.23)	4.00 (2.70)
BT	5.20 (2.51)	2.66 (2.49)

DN: dry-needling; L: lidocaine; BT: botulinum toxin

By assessing the other results, it is possible that Group 1 (DN) appeared to present a shorter period of relief from symptoms than that of the others, when the total study period was compared. Up to the 4-week time period, the patients in Groups 2 (L) and 3 (TB) showed less need to ingest rescue medication, which could be interpreted as more lasting effects.

With regard to local sensitivity, the results showed that there was a statistically significant difference among the groups, showing that the use of lidocaine or botulinum toxin made the technique less painful. Furthermore, the reduction in peripheral sensitization caused by the anesthetic effect would appear to minimize the effects of central sensitization.

Another important characteristic, inherent to the technique of injection in trigger points, would appear to be relief of symptoms provided after application.[32] Statistically, all the groups showed a similar behavior pattern with regard to reduction of headache complaint. Some patients, especially those in whom central sensitization could be observed, related post-application exacerbation of the symptoms, which has also been observed by other researchers.[5,15,22,27,43]

The probability of fast relief from symptoms enables this technique to be indicated successfully in cases of emergency. The decision of when to inject, as well as what to inject, should be taken on the basis of the individual characteristics of each case, and always in association with some other therapeutic modalities.[1,2,8,9,15,25,27,31-35]

Significant improvement was observed in pain during trigger point palpation from the time before to the time of ten minutes after injection, with extension to the other assessed periods. This shows the effectiveness of the injection technique on the reduction of symptoms and its importance in controlling myofascial pain. Furthermore, the absence of statistical significance between the tested groups emphasizes that all the tested techniques may be used successfully for this purpose.

Some studies have shown that the action of botulinum toxin could be retarded when the almost immediate effects provided by lidocaine or dry-needling are compared.[44]

Added to the findings of the other variables analyzed, such as the reduction in intensity, frequency and duration of the headache complaint (shown by the SSI values) and reduced ingestion of rescue medication (ibuprofen), they evidence very satisfactory results. Based on the findings of this study, other authors also showed that the use of regional blocks produces an effect of peripheral hypostimulation, interfering in the mechanisms of nociceptive impulse formation and transmission through the trigeminal system, reducing the pain and the chances of the pain becoming chronic.

Conclusions

It can be concluded that the substances tested have desirable effects on the studied disorders. The choice must be made based on characteristics, such as the previous use of other substances and their results, costs and discomfort. Important considerations like the chronic state of cases, resistance to conventional treatments, periodicity and dosage, and association of therapeutic modalities should be included in the prerequisites adopted when preparing treatment strategies. Considering its reduced cost, lidocaine could be adopted as a substance of choice, and botulinum toxin should be reserved for refractory cases, in which the expected effects could not be achieved.

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