



Trigger Point Infiltrations into the Temporal Muscles of Patients with Fibromyalgia and Headaches: A Randomized, Double-Blinded and Controlled Study

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Abstract

Aims: To compare the therapeutic effect of blocking trigger points in temporal muscles by using saline and an anesthetic agent among patients with masticatory myofascial pain syndrome, fibromyalgia and headaches and with non-infiltrated controls. **Methods:** One hundred women, aged 23 to 70 years old, were initially triaged. The seventy patients who experienced at least one trigger point in the temporal muscles were randomly divided into three groups, as follows: saline infiltration, anesthetic infiltration and control (non-infiltrated). **Results:** All of the patients with cranio cervical pain confirmed the presence of a headache. Temporal muscle tenderness occurred in 90% of patients, and 93% to 98% of the trigger points of the temporal muscles caused headache upon palpation. There was reduced facial pain intensity in 87.71% of the patients infiltrated with saline and 100% of the patients infiltrated with an anesthetic but not in the control group. The results were similar, considering the frequency of the headache. Regarding the intensity of the headache, infiltration with the saline and the anesthetic were both effective and did not exhibit significant differences, whereas significant differences were observed in the control group. **Conclusions:** Patients with fibromyalgia experience pain in the orofacial region and trigger points in the temporal muscles, which trigger a headache. Treatment with infiltration decreases facial pain and the frequency and intensity of headaches. There were no differences in treatment in terms of the infiltrated substance that was administered.

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Keywords

Headaches, Fibromyalgia, Infiltration, Trigger Point, Myofascial Pain Syndrome

Subject Areas: Neurology, Rheumatology

1. Introduction

Fibromyalgia (FM) is a nonarticular rheumatic syndrome that is characterized by chronic widespread pain with tender points upon palpation at specific tender sites on the body, which is in the absence of other apparent organic diseases. The classification criteria were described in 1990 by the American College of Rheumatology [1]. It is considered to be the second most common rheumatic disease, affecting mostly women. Many other diseases may be associated with FM, and most patients have other associated comorbidities [2]-[5].

Myofascial pain syndrome (MPS) is a common regional pain syndrome and is considered to be the most common pain complaint observed in medical practice. The pain symptoms result from hyperalgesia of small trigger points, which radiate pain to distant sites [6] [7]. MPS can affect the orofacial region, which is referred to as masticatory myofascial pain syndrome (MMPS). The intensity of the facial pain in FM patients is correlated with generalized muscle pain [8]. The presence of headaches in patients with FM is marked, and their symptoms may be manifested by referred pain from myofascial trigger points [9]-[13].

Anesthetic or saline infiltration on trigger points is a form of MMPS treatment. This treatment aims to decrease the facial pain intensity and may even reduce headache symptoms through pain modulation [12]-[20].

The current study aims to investigate the effectiveness of blocking trigger points using different solutions (saline versus anesthetic) on the temporal muscles of patients experiencing MMPS, FM and headache.

2. Materials and Methods

This study, which was approved by the Ethics Committee on Human Research of the Teaching Hospital of the Federal University of Paraná, was randomized, double-blinded and controlled.

The research was divided into two stages, which are illustrated in the flowchart in **Figure 1**. At each stage, the patients read and voluntarily signed an informed consent form.

Patients with FM, which was diagnosed according to the classification criteria of the American College of Rheumatology [1], and patients undergoing treatment from January 2007 to June 2008 at the FM outpatient clinic of the Teaching Hospital of the Federal University of Paraná were included in the first research stage. The exclusion criteria were the following: patients having their first visit and not having started treatment at the outpatient clinic; male patients; and an inability to read and/or understand the informed consent form.

The initial sample consisted of 100 female patients with FM, whose ages ranged from 23 to 70 years. The patients initially had a screening visit (first stage), and the participants selected for this study had treatment and follow-up visits (second stage).

In the first stage, the patients were evaluated for the presence of pain in the face and/or neck region and headaches. They were subsequently examined for trigger points on the temporal muscle (right and left), according to the methods described by Simons *et al.* [21]. The presence or absence of pain was scored using a numerical scale (0—absence of pain, 1—presence of tenderness, 2—presence of pain and 3—hyperarousal) [22]-[24]. The muscles examined were pressed until the nail bed of the examiner's index finger appeared whitish in color [25]. All patients triaged (100%) had some type of pain in the face and/or neck regions and the presence of a headache. Temporal muscle tenderness occurred in 90% of patients.

Although patients had trigger points in all temporal muscle groups, there was a reduced presence of these points in the right posterior (27 patients) and left posterior (29 patients) regions and an increased presence of these points in the left anterior (62 patients) and right anterior (61 patients) regions. Headache was induced by 93% to 98% of the trigger points upon palpation (**Table 1**).

In the second stage, the trigger points were treated with saline or anesthetic infiltration. The patients who were examined in the first stage of research and had at least one trigger point in one of the temporal muscle groups (right or left), regardless of the presence of headache, were included in the second stage of the study. The exclu-

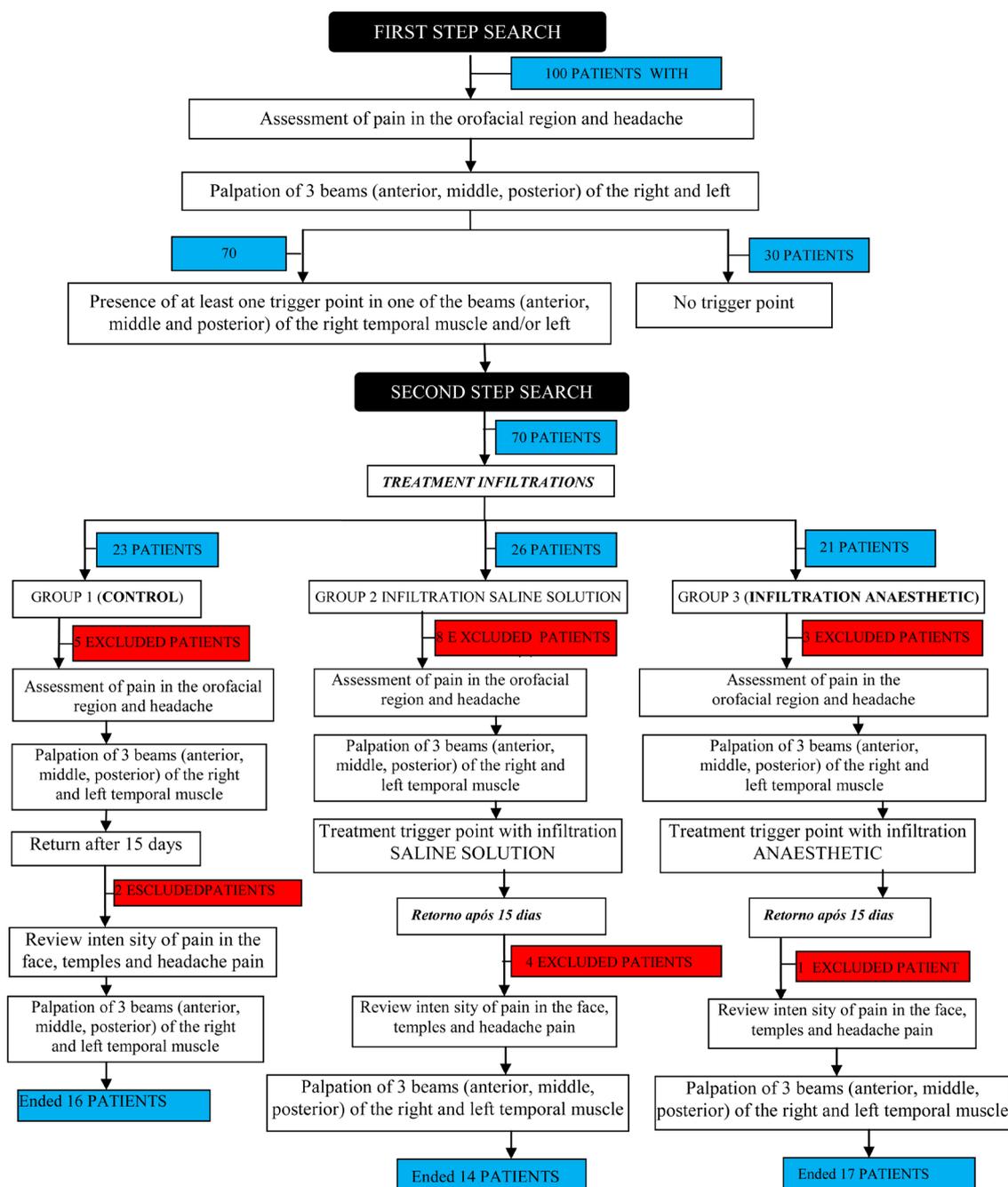


Figure 1. Flow chart of research stages.

sion criteria were the following: evidence of inflammatory rheumatic disease; cardiopathy or uncontrolled arterial hypertension; uncontrolled diabetes mellitus; blood dyscrasias; local infection; systemic infection; local skin changes; or a history of allergy to the anti-inflammatory medication prescribed following infiltration [6].

Seventy of the 100 patients examined in the first stage of the study were included in the second stage (treatment with infiltration), and these participants were randomly divided into three groups (the saline infiltration, anesthetic infiltration and control groups) using SIGMASTAT for Windows, version 2.0 (Systat Software, San Jose, CA, USA).

At the follow-up visit, the research subjects were reassessed regarding the effectiveness of the intervention used, which was compared to the state of the control patients who did not undergo therapeutic intervention.

Table 1. The results of the palpation of each temporal muscle group.

Temp. musc.	Muscle pain upon palpation					Presence of trigger points			Palpation causes headaches		
	0	1	2	3	n	No	Yes	n	No	Yes	n
Left post.	11 (11%)	40 (40%)	44 (44%)	5 (5%)	100	71 (71%)	29 (29%)	100	2 (7%)	27 (93%)	29
Left medial	5 (5%)	28 (28%)	56 (56%)	11 (11%)	100	52 (52%)	48 (48%)	100	3 (6%)	45 (94%)	48
Left ant.	2 (2%)	13 (13%)	60 (60%)	25 (25%)	100	38 (38%)	62 (62%)	100	1 (2%)	61 (98%)	62
Right post.	26 (26%)	43 (43%)	29 (29%)	2 (2%)	100	73 (73%)	27 (27%)	100	2 (7%)	25 (93%)	27
Right med.	12 (12%)	32 (32%)	51 (51%)	5 (5%)	100	58 (58%)	42 (42%)	100	2 (5%)	40 (95%)	42
Right ant.	3 (3%)	21 (21%)	49 (49%)	27 (27%)	100	39 (39%)	61 (61%)	100	2 (3%)	59 (97%)	61

temp. musc.—temporal muscle, left post.—left posterior, left ant.—left anterior, right post.—right posterior, right med.—right medial, right ant.—right anterior, n—total patients, 0—absence of pain, 1—presence of tenderness, 2—presence of pain, 3—hyperarousal.

The characteristics of the saline, anesthetic and control groups and the data for the discontinued patients are shown in [Figure 1](#).

The infiltration procedure was double-blinded and was performed in the saline and anesthetic groups with the patients lying down. The trigger points were located by manual palpation, the skin was disinfected with 70% liquid alcohol and a freezing spray (-40°C) was applied to prevent pain during the needle penetration [20] [21] [26] [27]. Carpule syringes with reflux and 30-G short needles were used in the procedure [6]. A volume of 0.2 ml to 0.5 ml of anesthetic or saline was administered to each trigger point [20] [25]. The infiltration procedures, local massage and temporal muscle stretching after the procedure were performed according to the methods described by Simons *et al.* [21] and other studies [24] [28]. Individuals from the saline and anesthetic groups received 100-mg nimesulide tablets, which were taken every 12 hours for two days. During the medication use, the patients were instructed to use a warm, wet compress for 10 to 15 minutes, three to four times a day; the compress could be replaced by submersion of the site of the infiltration in a warm bath [29].

3. Statistical Analysis

The Wilcoxon test was used to compare the intragroup results, and the Kruskal-Wallis test was used to compare the results between groups. The logistic regression model was used to compare the groups two-by-two regarding the probability of improvement, and this model was controlled for the patient age and adopted either the Wald test or the Fischer's exact test with Bonferroni correction, if the use of the Wald test was not possible.

4. Results

The results below pertain to records from the second stage, wherein the patients undergoing the infiltration procedure were analyzed by comparison with the control group.

4.1. Facial Pain Intensity

Both the saline and anesthetic treatments significantly reduced the facial pain intensity compared to the control group ($p = 0.004$ and $p < 0.001$, respectively; [Table 2](#)). There was a statistically significant difference in the two-by-two comparison of groups when the comparison was performed with the control group, with no difference between the groups treated with the saline and the anesthetic ($p = 0.003$ and $p = 0.005$, respectively; [Table 3](#)). There was a reduction in facial pain intensity in 85.71% of the patients treated with saline, 100% of the patients treated with the anesthetic and 43.75% of the control patients. There was a statistically significant difference in the two-by-two comparison of the groups regarding the reduction in facial pain intensity when the comparison was performed between the group treated with anesthetic and the control group ($p < 0.001$; [Table 3](#)).

4.2. Pain in the Temples or above the Ears

Only two subjects from the saline group, two from the control group and five from the anesthetic group reported having no pain in the temples or above the ears 15 days after the treatment. An improvement in symptoms oc-

Table 2. The comparison between treatment groups.

Group		N	Facial pain intensity		Weekly frequency of headaches		Headache intensity	
Saline	Pre-infiltration	14	7.8 ± 1.6		4.3 ± 2.4		8.6 ± 1.8	
	After 15 days	14	2.8 ± 3.7	0.004	2.1 ± 2.7	0.037	5.1 ± 4.0	0.008
	Reduction	14	5.0 ± 4.0		2.1 ± 3.3		3.5 ± 3.8	
Anesthetic	Pre-infiltration	17	6.5 ± 1.8		4.1 ± 1.9		7.8 ± 1.6	
	After 15 days	17	1.6 ± 2.1	<0.001	1.9 ± 1.7	0.002	4.4 ± 2.5	0.001
	Reduction	17	4.9 ± 1.9		2.2 ± 2.2		3.4 ± 2.8	
Control	Pre-infiltration	16	7.0 ± 1.8		2.9 ± 2.5		7.9 ± 2.4	
	After 15 days	16	5.8 ± 4.1	0.209	3.1 ± 2.3	0.919	6.6 ± 2.5	0.173
	Reduction	16	1.3 ± 3.6		-0.1 ± 1.5		1.3 ± 3.2	
				p^*		p^*		p^*

(^{*}) Nonparametric Wilcoxon signed-rank test; $p < 0.05$.

Table 3. The two-by-two comparison of groups.

Group comparisons	Facial pain intensity	Reduction of facial pain intensity	Pain in the temples or above the ears	Weekly frequency of headaches	Headache intensity
Saline × anesthetic	0.704	0.196	0.384	0.966	0.220
Saline × control	0.003	0.026	0.801	0.003	0.756
Anesthetic × control	0.005	< 0.001	0.204	0.002	0.112
	p^*	p^{**}	p^{***}	p^*	p^{***}

(^{*}) Mann-Whitney test, $p < 0.05$; (^{**}) Fisher's exact test with Bonferroni correction, $p < 0.017$; (^{***}) Wald test with logistic regression, $p < 0.05$.

occurred in 14.29% of the subjects treated with saline, 29.41% of the subjects treated with the anesthetic and 12.50% of the control group. When comparing the groups two by two, there was no statistically significant difference between the groups (Table 3).

4.3. Weekly Frequency of Headaches

There was a statistically significant reduction regarding the weekly frequency of headaches in both the saline and anesthetic groups ($p = 0.037$ and $p = 0.002$, respectively; Table 2), unlike the control group. There was a statistically significant difference when the two-by-two comparison of the groups was performed with the control group, with no difference between the groups treated with the saline and anesthetic ($p = 0.003$ and 0.002 , respectively; Table 3).

4.4. Headache Intensity

The saline and anesthetic treatments were both effective regarding their effect on headache intensity ($p = 0.008$ and $p = 0.001$, respectively; Table 2), unlike the control group. There was a reduction in the headache intensity in 64.29% of the patients treated with saline, 82.35% of patients treated with the anesthetic and 56.25% of the control group. There was no statistically significant difference between the groups when compared two by two (Table 3).

5. Discussion

The study conducted involved a sample of female patients only because FM is a chronic pain syndrome primarily affecting women [2]-[4]. There was an agreement with the age of disease progression, which was 20 to 60 years [17] [30] [31]. The mean age was close to that of recent studies reporting that the prevalence among

women reaches a maximum peak at approximately 55 to 64 years, which are ages close to the occurrence of menopause, during which women experience a significant hormonal decrease; this fact reinforces the possible effects of hormonal factors [2] [32] [33].

The high percentage (100%) of patients with pain in some region of the face and/or neck presumably occurred because this study was specifically designed to evaluate pain in that region and was often overlooked by the lack of emphasis given by the examiner, especially when the pain was not only a localized problem but a condition with generalized muscle pain, such as FM [34]. Temporal muscle tenderness in these patients was identified by a report of pain in the temples or above the ears, which confirmed a high sensitivity to temporal muscle pain in patients with MPS [7]. The strong presence of both MMPS and a headache confirms the association of FM with other conditions. The high prevalence of both conditions in this study reinforces the need for an individual assessment of each patient to identify the comorbidities, thereby affecting the quantification of symptoms and assisting in the treatment modality and, consequently, in disease control [35] [36].

The percentage of patients with headache in our study (100%) exceeds that reported by some authors (53% to 82%), but it is in agreement with the results of other studies that report over 91% of patients with headaches [10] [11].

At least one trigger point was found on the temporal muscle in 70% of patients upon palpation at the first research stage, confirming the association with MPS; this value is greater than some accounts that report 18% [1] [37] and is in agreement with the values reported in other accounts (68% to 72%) [38] [39]. The high percentage of patients with MMPS confirms the association of temporomandibular disorders in patients with FM, thereby reinforcing the hypothesis that these disorders may cause the facial pain in these patients [9] [33]. The radiating pain of these trigger points can cause headache and toothache [11] [21].

The headache may be a manifestation of muscle tenderness [9] [40]. The radiating pain caused by trigger points located in the temporal muscle may manifest as a headache [11] [15]-[17] [21]. This finding was confirmed in the present study, which found a high percentage of trigger points in temporal muscles that triggered a headache upon palpation, thus allowing its classification as a headache secondary to MPS. The presence of trigger points in these areas is plausible because it is the most typical location of migraine pain. Furthermore, it is among the most common areas of radiating pain in patients with headaches, including chronic tension headaches [12] [14] [16].

The infiltration of trigger points in the temporal muscle was used to test the impact of this form of treatment on myofascial pain and headache, thereby representing one of the indicated forms of treatment [37] [41]. Although there are reports that the infiltration procedure is necessary in only 20% to 25% of patients with MPS, it is considered to be the most effective treatment [27] [42].

The amount of anesthetic used within each trigger point was approximately 0.2 ml to 0.5 ml of 2% lidocaine without a vasoconstrictor [6] [41]. The anesthetic of choice, as in other studies, was lidocaine. It has been proven that lidocaine causes necrosis of the infiltrated muscle tissue, but regeneration occurs rapidly (within 16 days) [6] [23] [24] [28] [40]-[43].

Muscle stretching following the infiltration procedure was used as part of the treatment for increasing the treatment efficacy [6] [27]. Although studies have been conducted without the stretching and heat treatment after the infiltration procedure [44], an anti-inflammatory medication was used for 48 hours along with a warm, wet compress to minimize the pain following the infiltration procedure, which was in addition to hemostasis care. An anti-inflammatory medication was not used in the control group because the patients were already being treated at an FM outpatient clinic and had been undergoing medical treatment without observing any effects on their pain. The failure to use a warm, wet compress may have affected the results observed in the control group.

In the present study, the local anesthetic and saline were both effective for the trigger point treatment [27] [45]. Both groups showed a reduction in pain intensity when compared to the control group, with no statistically significant difference between these treatments. The control group also showed an improvement, although this result did not reach statistical significance. However, there are studies showing greater effectiveness of the anesthetic and treatments without infiltration, in addition to different comparisons regarding the type of solution and also involving a dry needling approach [26] [37] [42] [45]-[47]. However, there is a consensus that the treatment effectiveness is unrelated to the type of solution injected. The relief from pain most likely results from the needle contact with the trigger point, which breaks the vicious cycle of pain [29] [40] [46].

Following the treatment, decreased pain was observed in all temporal muscle groups examined, and this finding was confirmed upon palpation. There was no improvement in the pain in the temples or above the ears, ac-

ording to the patients' verbal reports. We hypothesize that this effect, which is not observed in the present study, may be related not only to a treatment failure at the distribution points but also to depressive symptoms and cognitive and memory changes, which are often observed in patients with FM and make it difficult for them to report their pain [6] [48]-[50].

The current study showed that the infiltration of an anesthetic and saline caused a reduction in both the intensity and frequency of headaches compared to the control group, without a statistically significant difference between the two treatment groups. This study reinforces the evidence that the treatments for muscles decrease the symptoms of headache through a central mechanism of pain modulation [12] [14]-[20].

Our study supports other evidence that FM patients experience pain in the orofacial region and that trigger points in the temporal muscles correlate with the occurrence of headaches. Although no other study to date has addressed the infiltration of trigger points in the temporal muscles of FM patients as a form of treatment, we suggest the application of this approach using either saline or an anesthetic to abolish or minimize orofacial pain and headaches in these patients.

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