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Effect of lidocaine patches on upper trapezius EMG activity and pain intensity in patients with myofascial trigger points: A randomized clinical study

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Abstract

Objective. To compare the effects of 5% lidocaine patches and placebo patches on pain intensity and electromyographic (EMG) activity of an active myofascial trigger point (MTrP) of the upper trapezius muscle. ***Materials and methods.*** Thirty-six patients with a MTrP in the upper trapezius muscle were randomly divided into two groups: 20 patients received lidocaine patches (lidocaine group) and 16 patients received placebo patches (placebo group). They used the patches for 12 h each day, for 2 weeks. The patch was applied to the skin over the upper trapezius MTrP. Spontaneous pain, pressure pain thresholds, pain provoked by a 4-kg pressure applied to the MTrP and trapezius EMG activity were measured before and after treatment. ***Results.*** Baseline spontaneous pain values were similar in both groups and significantly lower in the lidocaine group than the placebo group after treatment. The baseline pressure pain threshold was significantly lower in the lidocaine group, but after treatment it was significantly higher in this group. Baseline and final values of the pain provoked by a 4-kg pressure showed no significant difference between the groups. Baseline EMG activity at rest and during swallowing of saliva was significantly higher in the lidocaine group, but no significant difference was observed after treatment. Baseline EMG activity during maximum voluntary clenching was similar in both groups, but significantly higher in the lidocaine group after treatment. ***Conclusions.*** These clinical and EMG results support the use of 5% lidocaine patches for treating patients with MTrP of the upper trapezius muscle.

Key Words: *algometry, 5% lidocaine patches, electromyography, myofascial pain, trigger point*

Introduction

Clinicians often treat patients with pain due to myofascial pain syndrome (MPS), which is characterized by muscle pain caused by myofascial trigger points (MTrPs). A MTrP is a localized hyperirritable spot in a palpable taut band of skeletal muscle [1,2], which was originally defined by Travell and Simons [3] and Simons [4].

The MTrP mediates a local twitch response under snapping palpation and, when stimulated locally by compression or needle penetration, causes pain, tenderness, autonomic phenomena and motor dysfunction, not only locally but also distally (referred pain) in a target area that is specific to each muscle [5-7].

MPS, whether alone or in association with other algogenic syndromes, causes disability not only from pain but also from weakness and severe limitation in the range of motion of the affected muscles [8]. As a consequence, patients may experience impairment of their work, social activities and quality-of-life [7].

Management of MPS consists of invasive and non-invasive treatment interventions [1], in conjunction with identification and removal of perpetuating factors [2,7,9,10]. Invasive procedures include dry needling of MTrPs and injection with botulinum toxin or local anesthetic agents such as lidocaine [2]. Some non-invasive options (e.g. stretch and spray, massage, transcutaneous electrical nerve stimulation, local heat) have been proposed for the treatment of MPS

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[7,11,12]. Manual treatment of active MTrPs may reduce spontaneous pain and increase the pressure pain threshold in patients with shoulder impingement [13]. Manual techniques on upper trapezius with latent trigger point seemed to improve the cervical range of motion and the pressure pain sensitivity [14]. Although effective, injection is an invasive and unpleasant procedure for patients, which also requires a skillful technique. For patients with MPS, a topical lidocaine patch may offer clinical benefit. The 5% lidocaine patch has been approved by the US Food and Drug Administration for the treatment of post-herpetic neuralgia [15].

Lidocaine is an anesthetic that influences the initiation and transmission of nerve impulses. The absorption of lidocaine after application of the 5% lidocaine patch over the skin can produce an analgesic effect without causing local anesthesia. Because the 5% lidocaine patch interrupts pain signals in peripheral nociceptors, it may be used as a localized, targeted approach for some painful conditions, including MPS [16].

We found only two recent randomized controlled studies that evaluated the efficacy of local treatment with the 5% lidocaine patch in patients with MPS. Affaitati et al. [2] compared the effects of a placebo patch and the 5% lidocaine patch in the treatment of MPS. These authors investigated multiple muscles—including the upper trapezius—and found that the 5% lidocaine patch was superior to the placebo patch. Subjective symptoms decreased significantly and pain thresholds increased significantly with the lidocaine patch. However, they only investigated the short-term effect of the lidocaine patch for 9 days. Recently, Lin et al. [1] applied a lidocaine patch only on the trapezius muscle for a period of 7 days and evaluated its effects on day 7, day 14 and day 28. They found that pain intensity (assessed by verbal rating scale) was significantly decreased at day 14 in the lidocaine patch group compared to the placebo patch group. However, neither of these studies simultaneously recorded electromyographic (EMG) activity in the upper trapezius muscle, where the patches were applied.

Active MTrPs are characterized by multiple sensitive and active loci, representing sensitized nociceptors and sensitized motor end plates, respectively. Atypical end plate behavior is characterized by spontaneous low-amplitude noise combined with intermittent higher amplitude spikes. This is not observed at normal end plates and is the result of the spontaneous release of acetylcholine, suggesting end plate hyperactivity [17]. Furthermore, abnormal spontaneous electrical activities, spike activities and local twitch responses have been observed at MTrPs [18,19].

Information regarding a possible correlation of clinical symptoms and EMG activity in patients with MPS, because of the presence of a trigger point, is not available. The upper trapezius is one of the muscles most commonly affected by MPS [20,21]. Therefore, our study was designed to compare the short-term effect of topical 5% lidocaine patches and placebo patches on the pain intensity and EMG activity related to MTrPs in the upper trapezius muscle.

Materials and methods

Subjects

One hundred and eighty-seven consecutive patients seeking treatment for orofacial pain were referred to the University of Chile Temporomandibular Disorders and Orofacial Pain Center over a 6-month period. These patients were subjected to a routine stomatognathic examination. A dentist trained in the diagnosis of orofacial pain and temporomandibular joint disorders performed a clinical and functional examination, which included neck structures. To be included in the study, patients must had a history of regional muscle pain caused by at least one MTrP in the upper trapezius muscle, for at least 1 month, and of intensity ≥4 (measured by means of a horizontal 0–10 numeric rating scale with 0 labeled as 'no pain' and 10 as 'worst imaginable pain'). The pain also had to conform to the following characteristic referred pain, according to Travell and Simons [3] criteria: (1) pain recognition: if the patient recognizes pain is caused by pressure to the upper trapezius muscle, then an MTrP could be considered the cause of the orofacial pain; (2) palpable taut muscle band: the presence of a taut band associated with pain; (3) characteristically referred pain, reproducible during upper trapezius palpation; and (4) painful limitation of the range of movement.

Patients were excluded if they had hypersensitivity to lidocaine or to any of the excipients of the patch; known hypersensitivity to other local amide-type anesthetics, (e.g. bupivacaine, etidocaine, mepivacaine and prilocaine); fibromyalgia; cervical spine and/or cervical degenerative diseases; rheumatic illnesses; cardiac arrhythmia; arterial hypertension; severe cardiac impairment; severe renal impairment or severe hepatic impairment; history of cervical spine surgery; pregnancy or breast-feeding; neuropsychiatric conditions and/or cognitive and/or physical alterations which could interfere with the indicated self-placement of the patches according to the therapeutic design of the study; or if the area of skin where the patch was to be applied was inflamed or injured; for example, the presence of active herpes zoster lesions, atopic dermatitis or wounds. Also, patients should not have taken antidepressant, anti-epileptic, anti-convulsive, muscle-relaxing or hypnotic medication, opioids or any kind of sedation, for at least 1 month before the

day of recruitment and for at least 3 days for NSAIDs and acetaminophen. None of the patients had previously used any local topical treatment.

Forty MPS patients were invited to participate in the study. One patient refused to participate and another was allergic to the excipients of the lidocaine patch. The sample was randomly divided into two groups: the lidocaine group ($n = 20$), who received 5% lidocaine patches; and the placebo group ($n = 18$), who received placebo patches (control group). In the placebo group, one patient was lost to follow-up and one patient was excluded because of noise interference in the EMG activity. Finally, 20 patients in the lidocaine group (four men and 16 women, mean age = 35.5 years) and 16 patients in the placebo group (one man and 15 women, mean age = 31.7 years) were included in the data analysis (Figure 1).

In order to maintain the double-blind conditions of the study, the patch envelopes were re-labelled with study instructions. Randomization was performed using software available in www.randomizer.org and the procedure was carried out by an assistant. The investigators had no access to the randomization process or to the criteria for patient assignment.

Working chart

Recruitment (day 0).. Patients were recruited from the pain clinic. Before the informed consent form was signed, patients were given information about the research project. Patients were warned of possible adverse effects from use of the 5% lidocaine patches, according to the accompanying product information. This warning was repeated in the informed consent form. The ethics committee of the Universidad Nacional Andrés Bello, Faculty of Dentistry approved the study protocol.

Baseline (day 1).. In both groups, patients were asked to average their spontaneous pain intensity during the last month, measured on a numeric rating scale (0–10) and to draw their pain pattern on a body diagram. Subsequently, the pressure pain threshold (PPT)—measured in kilograms using an algometer (Wagner Instruments, Force Dial^{TM} FDK/FDN, Greenwich, CT, USA)—on the upper trapezius trigger point was evaluated. Finally, the pain intensity provoked by a 4-kg pressure with the algometer on the same area was measured, again using a numeric rating scale (0–10) (Figure 2). In healthy patients this 4-kg

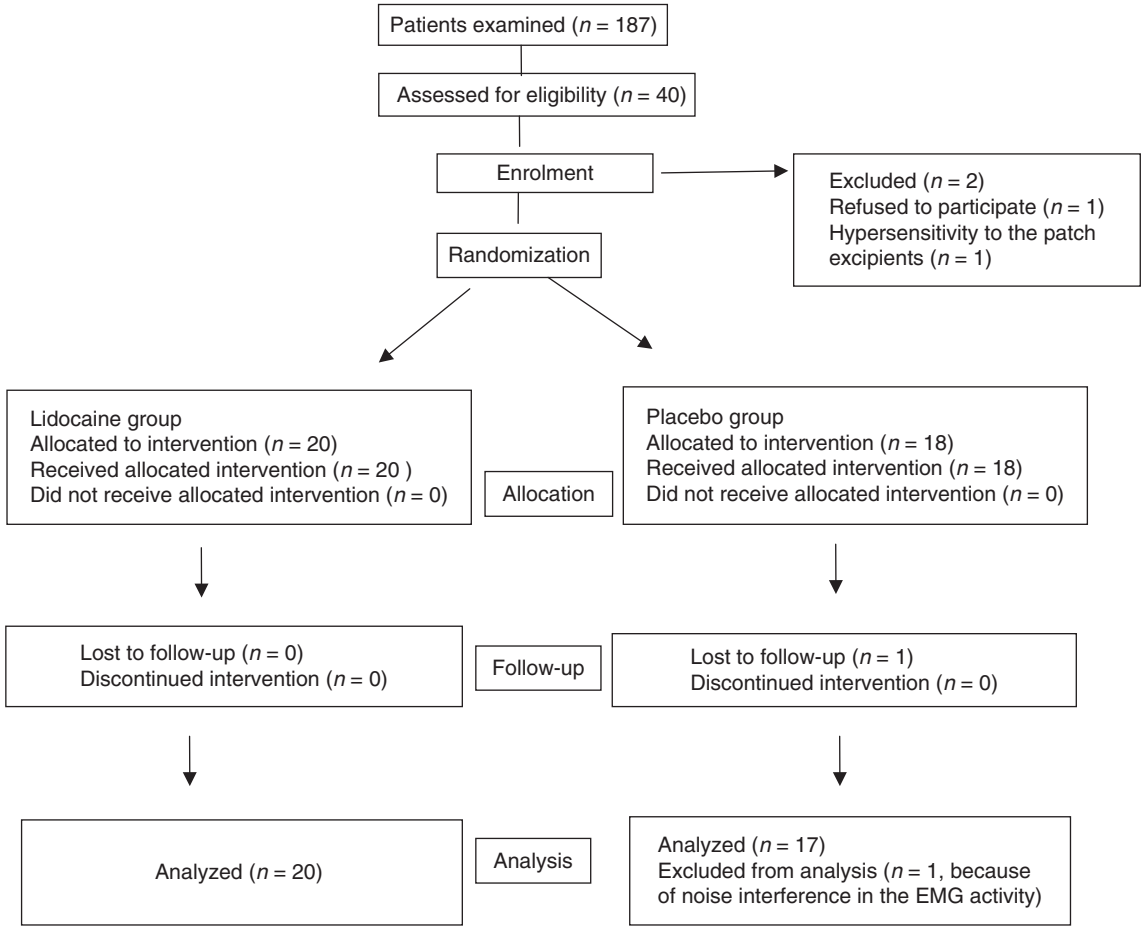

Figure 1. Flow chart of the study protocol.

Figure 2. Pressure pain threshold (PPT) measured at trapezius muscle, using a digital algometer (Wagner Instruments, Force Dial^{TM} FDK/FDN, Greenwich, CT, USA).

Figure 3. Position of electrodes on the upper trapezius muscle.

pressure applied with the algometer produced no pain [20].

At the same session, bipolar surface electrodes (BioFLEX: BioResearch Associates, Inc., Brown Deer, WI) were located on the upper trapezius muscle. The skin area was cleaned with alcohol to reduce skin impedance and to enhance signal conductivity. The electrodes were placed over the upper trapezius muscle on the painful area of the palpable taut muscle band, slightly behind the area between the neck and shoulder. A wide surface ground electrode was fixed on the forehead. The position of the electrodes was the same during all EMG recordings (Figure 3).

The EMG signals were amplified (Model 7P5B preamplifier, Grass Instrument Co. Quincy, MA), rectified and then integrated. During EMG recording at rest and during swallowing, the signals were integrated with a time constant of 0.1 s, whereas during maximum voluntary clenching in maximum intercuspation, the signals were integrated with a time constant of 1 s. EMG activity was registered online in a computer devoted solely to the acquisition and processing of EMG signals. EMG activity was recorded while the patient was in the standing position, maintaining their stance with feet at 10 cm apart, with their eyes open, looking straight ahead. The self-balanced position was obtained by having each patient standing with their visual axis horizontal with no external intervention or modification of their posture. The upright position was chosen to register EMG activity because it allowed researchers a better standardization of the recordings.

All patients of both groups underwent three EMG recordings of the upper trapezius muscle in a single session: at rest, during swallowing of saliva and during maximum voluntary clenching in the intercuspal position. The mean value of three recordings obtained for each patient at each task was used. EMG activity of the suprahyoid muscles was recorded because it is an excellent marker of the beginning and the end of EMG activity during swallowing of saliva. This allowed us to identify the start and the end of EMG recording during swallowing of saliva in the trapezius muscle.

Immediately after baseline recordings, the investigator cut the patch (lidocaine or placebo) into four pieces and applied one piece to the skin overlying the trigger point. Thirteen patches were given to each patient. The researcher gave oral and written instructions to the patient in order to use the patch for 12 h continuously and then to remove it for 12 h. In order to ensure good attachment of the patch to the skin, micropore paper tape was applied over the edges. This procedure was repeated every day for 14 days.

The lidocaine patch is a 10×14 cm^2, white hydrogel plaster containing adhesive material, which is applied to a non-woven polyethylene terephthalate backing embossed with 5% lidocaine and covered with a polyethylene terephthalate film release liner. It contains 700 mg (5% w/w) lidocaine as an active ingredient.

Cutting the lidocaine patch is an approved use of the product according to the manufacturer's prescribing information and does not interfere with drug delivery,

because distribution of the drug is homogeneous throughout the patch.

At the end of the 14th day, the patients came to the laboratory for the second EMG recording session. The potential for examiner bias was controlled for in our study, as each researcher was blinded with respect to the allocation of the lidocaine or placebo patches.

The recommendation is that a maximum of three patches be used at the same time, over healthy skin, and should be placed for 12 h and then withdrawn for 12 h each day. When a 5% lidocaine patch is used according to the maximum recommended dose, ~3 ± 2% of the total applied lidocaine dose is systemically available, whether for single or multiple administration.

After Treatment (day 14).. All patients were asked to rate the intensity of their spontaneous pain (NRS) and the pain provoked by a 4-kg pressure with the algometer on the same area (NRS) and to draw their pain pattern on a body diagram. In addition, the pressure pain threshold was measured. All recordings were carried out in the same way as on day 1.

All patients of both groups underwent three EMG recordings of the upper trapezius muscle: at rest, during swallowing of saliva and during maximum voluntary clenching in the intercuspal position. All recordings were carried out in the same way as on day 1.

Finally, all patients were asked about possible adverse events, which were recorded on a Spanish version of the CIOMS I (Council for International Organizations of Medical Sciences) form for adverse events.

Data analysis

The mean value of the three EMG curves obtained for each patient at each task was used. Task-to-task variability in the trapezius muscle was ≤29.20%; during swallowing of saliva was ≤30%; and during maximum voluntary clenching was ≤27%.

Spontaneous pain, pain provoked by a 4-kg pressure and EMG data did not present a normal distribution (Shapiro-Wilk test), so the comparisons were made using the Wilcoxon Signed-Rank test. Pressure pain threshold data presented a normal distribution (Shapiro-Wilk test), so the comparisons were performed using the two-sample *t*-test. A value of $p < 0.05$ was considered statistically significant. The data were analyzed using STATA, version 13.0 (College Station, TX).

Results

Clinical pain measurements

Baseline and final spontaneous pain values in each group are shown in Figure 4. When comparing initial vs final values in the lidocaine group and the placebo group, a significant reduction was observed in both groups (Table I). The comparison of initial values between both groups did not show a significant difference. However, the comparison of final values between both groups did show a significant difference.

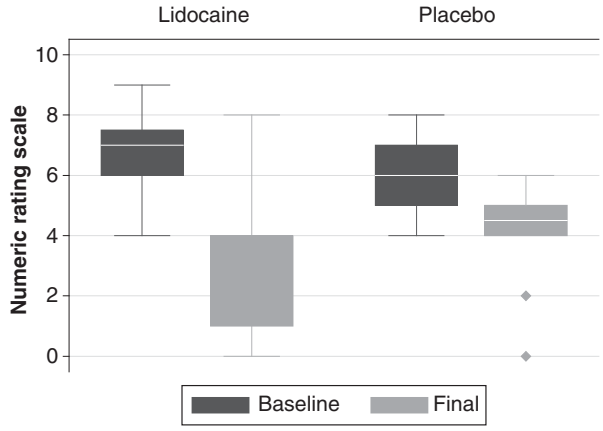

Figure 4. Baseline and final spontaneous pain (NRS) in both lidocaine and placebo groups. In this figure and in the next figures, the box and whisker plots demonstrate the median values, with the boxes extending to the 25th and 75th percentiles and the whiskers extending to the minimum and maximum values.

Baseline and final pressure pain threshold values in each group are shown in Figure 5. When comparing initial vs final values in the lidocaine group, a significant increase was observed (Table I), whereas no significant difference was observed in the placebo group. Baseline pressure pain threshold value was significantly lower in the lidocaine group, whereas after treatment it was significantly higher in the lidocaine group.

Baseline and final pain values reported while applying a 4-kg pressure are shown in Figure 6. When comparing initial vs final values in both the lidocaine group and the placebo group, a significant reduction was observed in both groups (Table I). The comparison

Table I. Comparison (probability figures) of clinical pain measurements in the trapezius trigger point zone.

	Placebo initial	Lidocaine final
Spontaneous pain		
Lidocaine initial	0.1096 NS	0.0001 **
Placebo final	0.0006 **	0.0388 *
Pressure pain Thresholds		
Lidocaine initial	0.0437 *	0.0000 **
Placebo final	0.3124 NS	0.0090 **
Pain provoked by a 4- kg pressure		
Lidocaine initial	0.0848 NS	0.0001 **
Placebo final	0.0420 *	0.2840 NS

Spontaneous pain (Wilcoxon Signed-Rank test).
Pressure pain thresholds (Two-sample *t*-test).
Pain provoked by a 4-kg pressure (Wilcoxon Signed-Rank test).
* $p < 0.05$; ** $p < 0.01$; NS, Not significant.

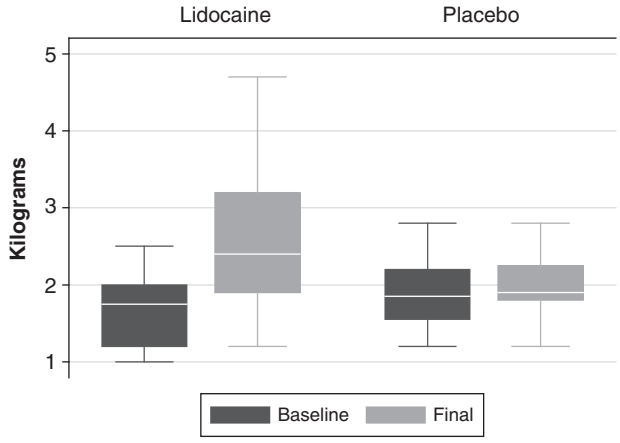

Figure 5. Baseline and final pressure pain threshold (kg) in both lidocaine and placebo groups.

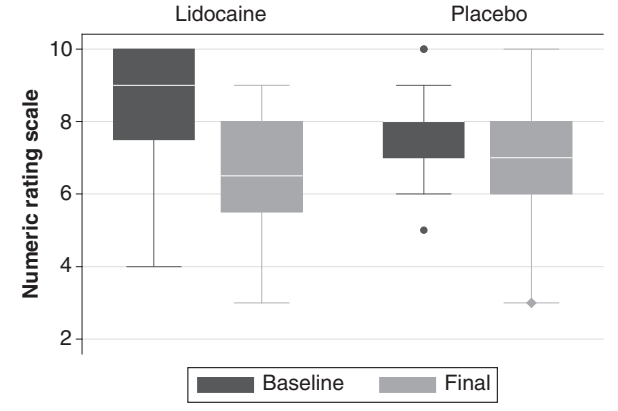

Figure 6. Baseline and final pain reported (NRS) while applying a 4-kg pressure in both lidocaine and placebo groups.

of initial values between both groups as well as between final values did not show a significant difference.

Electromyographic activity

Baseline and final EMG values for the upper trapezius muscle at rest are shown in Figure 7. When comparing initial vs final values in the lidocaine group, a significant reduction was observed (Table II), whereas the placebo group showed no significant difference. The comparison of initial values between both groups showed a significant difference. However, the comparison of final values between both groups did not show a significant difference.

Table II. Comparison (probability figures) of EMG activity in the trapezius trigger point zone (Wilcoxon Signed-Rank test).

	Placebo initial	Lidocaine final
At rest		
Lidocaine initial	0.0201*	0.0012 **
Placebo final	0.4691 NS	0.5038 NS
Saliva swallowing		
Lidocaine initial	0.0201*	0.0045**
Placebo final	0.6791 NS	0.2518 NS
Maximum voluntary clenching		
Lidocaine initial	0.1812 NS	0.9108 NS
Placebo final	0.2553 NS	0.0370*

*$p < 0.05$; **$p < 0.01$; NS, Not significant.

Baseline and final EMG values of the upper trapezius muscle during swallowing of saliva are shown in Figure 8. When comparing initial vs final values in the lidocaine group, a significant diminution was observed (Table II), whereas the placebo group did not show a significant difference. The comparison of initial values between both groups showed a significant difference. The comparison of final values between both groups did not show a significant difference.

Baseline and final EMG values of the upper trapezius muscle during maximum voluntary clenching are shown in Figure 9. When comparing initial vs final values in each of the two groups, EMG activity did not show a significant difference (Table II). The comparison of initial values between both groups did not show a significant difference. The comparison of final values between both groups showed a significant difference.

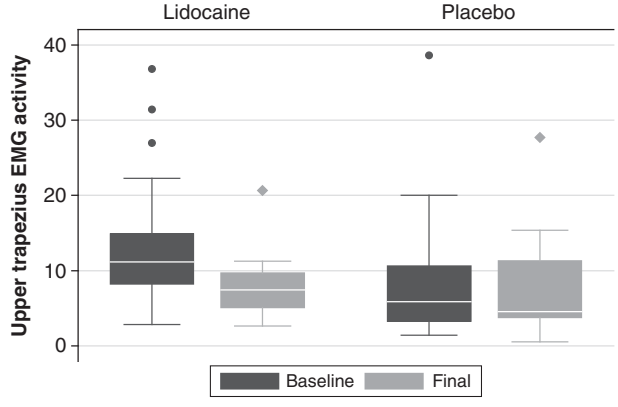

Figure 7. Baseline and final trapezius EMG activity at rest in both lidocaine and placebo groups.

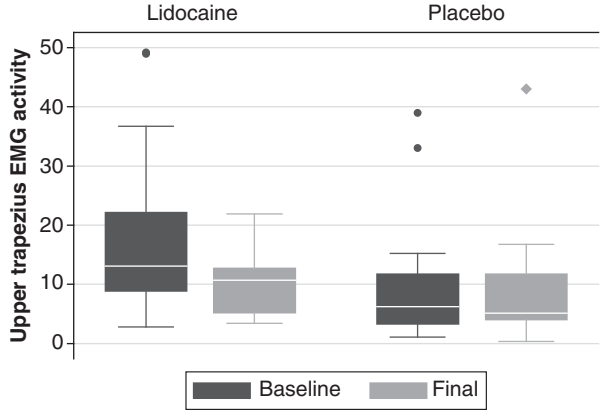

Figure 8. Baseline and final trapezius EMG activity during swallowing of saliva in both lidocaine and placebo groups.

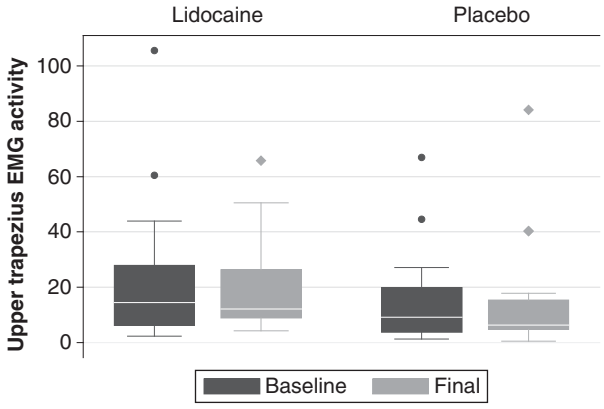

Figure 9. Baseline and final trapezius EMG activity during maximum voluntary clenching in both lidocaine and placebo groups.

Adverse events

No systemic adverse events were reported by the patients in any treatment group. However, slight local transitory adverse events were reported: seven patients in the lidocaine group and 10 in the placebo group reported skin itching under the patch. In the placebo group, three patients felt skin itching for 1 day after patch application; three patients felt it for 3 days; and four patients felt it for the whole 14-day period. Within the lidocaine group, three patients felt skin itching for 1 day after patch application; three patients felt it for 3 days; and one patient felt it for the whole 14-day period. In both groups and in all cases the skin itching lasted a few minutes after patch application.

Discussion

The major finding of the present study was the significant decrease of upper trapezius EMG at rest and during swallowing of saliva after treatment in the lidocaine group, compared to the placebo group. The authors believe this to be the first report showing the clinical and EMG effects of lidocaine patches in the upper trapezius muscle.

Baseline spontaneous pain significantly decreased in both groups, which suggests a placebo effect simply from the placement of the patch. Nevertheless, the lidocaine group showed a greater spontaneous pain reduction after treatment than the placebo group. This is in agreement with previous reports [1,2].

Baseline pressure pain threshold values were significantly lower in the lidocaine group than in the placebo group. Although randomization was carried out correctly, this difference could compromise the results. The pressure pain threshold after treatment was significantly higher in the lidocaine group than in the placebo group, which disagrees with the findings reported by Lin et al. [1]. Our results suggest that pressure pain threshold values are clinical correlates with an improvement of allodynia symptoms in the lidocaine group.

The baseline and final pain intensities (NRS) provoked by a 4-kg pressure did not show a significant difference between the groups. This could be explained by an overall placebo effect in the sample studied. Nevertheless, the decrease after treatment was more pronounced in the lidocaine group (Figure 6). This result cannot be compared with other studies because it is the first study in which provoked pain was recorded.

Clinical and EMG effects observed with the lidocaine patches are probably the result of the blocking action of the drug on voltage-gated sodium channels in nerve terminals in the trigger point [4,17,21,22]. Lidocaine binds to sodium channels and blocks nerve conduction [23,24]. Sodium channel block induces analgesic effects on neuropathic pain by suppressing hyperactivity in peripheral neurons, such as spontaneous ectopic discharges [25]. The lidocaine-induced reduction in sensory input from the trigger point would not only improve local symptoms and local tenderness, but also indirectly decrease symptoms in the target area by limiting the reflex mechanism responsible for the referred phenomena [2]. These effects could reduce central hypersensitivity, thereby producing a reduction in allodynia, as demonstrated by the increased pressure pain threshold upon the application of 4-kg pressure, a non-nociceptive stimulus. This agrees with a previous report which found that lidocaine produces better results in patients with mechanical allodynia at baseline than in those who did not have this symptom [3].

Several reports show substantial evidence of the presence of *spontaneous electrical activity* in the TrPs [17,18,26-28]. The reduction of trapezius EMG activity at rest and during swallowing of saliva in the lidocaine group is in agreement with the findings of Bahadir et al. [29], who found that ultrasound or local injection of lidocaine were equally effective in lowering the spontaneous electrical activity. Chen et al. [30] also found decreased spontaneous electrical activity after dry needling. Other studies also showed decreased spontaneous electric activity of TrP after administration of phentolamine and calcium channel blockers [31,32]. Therefore, it is reasonable that, in a successful treatment by applying lidocaine patches, clinical improvement of symptoms is accompanied by a decrease of EMG activity.

The therapeutic effect of lidocaine is not likely to be the result of systemic absorption, which has been shown to be minimal [33,34]. In fact, following the application of a 5% lidocaine patch on a maximal skin surface of 420 cm^2 (corresponding to the application of three whole patches) for 12 h, the mean (SD) maximal plasma concentration of lidocaine would be 0.128 (0.063) μg/mL (10-times less than the minimal plasma therapeutic concentration used for cardiac arrhythmias) [35]. Considering that the skin surface undergoing daily treatment in our study

was 35 cm^2, the systemic lidocaine absorption can be regarded as minimal.

The absence of significant EMG change during maximal voluntary clenching suggests that the peripheral effect of lidocaine patches might be obscured by the predominant influence of the suprasegmentary structures on the motor neuron pools that control activity of the trapezius muscles [36].

No systemic adverse events were reported by the patients in either group. However, slight transitory adverse events were reported. Skin itching under the patch, which was mainly transitory, occurred in 52.6% of patients in the placebo group and in 38.6% of the lidocaine group. The itching was reported as bearable and disappeared without treatment. The fact that minimal adverse effects were perceived by the patients supports the idea that self-administration of lidocaine patches is a safe therapeutic tool, under the direct supervision of a healthcare professional and as part of a much more comprehensive treatment scheme.

Finally, the sample size and duration of treatment should be recognized as limitations of our study. The long-term effect of topical 5% lidocaine patches for patients with MTrP should be evaluated in upcoming studies.

Conclusions

- Our study provides evidence that baseline upper trapezius EMG activity at rest and during swallowing of saliva significantly decreases after 14 days of lidocaine patch application.
- This finding is related to the significant reduction of spontaneous pain, pressure pain threshold and the pain elicited by a pressure of 4 kg on the trapezius muscle trigger point.
- Clinical and EMG results support the use of 5% lidocaine patches for the treatment of patients with MPS.

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***Declaration of interest*:** The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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