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Effectiveness of dry needling on the local pressure pain threshold in patients with masticatory myofascial pain. Systematic review and preliminary clinical trial

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ABSTRACT

Objective: To systematically review the literature to identify controlled clinical trials evaluating the effectiveness of deep dry needling (DDN) in the treatment of patients with chronic masticatory myofascial pain (MMP).

Methods: The sample size for a clinical trial was calculated and involved five patients who consecutively presented for treatment of MMP. The percentage of change in the means of three consecutive measurements of the pressure pain threshold (PPT) of myofascial trigger points (MTPs) was calculated and the statistical significance of this difference evaluated using the Wilcoxon test.

Results: Twenty-five studies were considered for inclusion based on title and abstract. Only 2 studies met the inclusion criteria and were used to calculate the sample size. DDN significantly increased (p = 0.04) the PPT in MTP (44.6%) compared with sham procedure (−5.5%).

Conclusion: Patients with chronic MMP treated with DDN of MTPs showed an increase in PPT measurements on the experimental side.

Abbreviations: CGRP: calcitonin gene-related peptide; DC/TMD: diagnostic criteria for temporomandibular disorders; DDN: deep dry needling; DN: dry needling; LILACS: Latin American and Caribbean Health Sciences; MMP: masticatory myofascial pain; MTP: myofascial trigger point; MTPs: myofascial trigger points; PPT: pressure pain threshold; RCTs: randomized clinical trials; SciELO: Scientific Electronic Library Online; SP: Substance P; TMD: temporomandibular disorders

KEYWORDS

Dry needling; myofascial trigger point; myofascial pain; pressure pain threshold; temporomandibular disorder

Introduction

According to the recently published Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) [1], the diagnosis of masticatory myalgias can be divided into at least two mutually exclusive diagnostic subgroups: local myalgia and myofascial pain. Local myalgia is defined as pain localized in the site of muscle palpation, replicating the patient’s main complaint of pain and aggravated by mandibular, functional or parafunctional movements. Diagnosis of myofascial pain requires, in addition to the previously described criteria for local myalgia, that pain is referred beyond the original site of muscle palpation [1]. Referred pain was reported for 85% of a sample of 230 temporomandibular disorder (TMD) patients when manual palpation pressure was maintained on the chewing muscles [2]. Among the extraoral sites of muscle palpation used in the DC/TMD clinical exam, the masseter muscle is a common source of referred pain for the orofacial region [3].

This referred pain usually comes from tense, palpable, hypersensitive muscle bands, called myofascial trigger points (MTPs), generating distinct therapeutic possibilities and prognoses. The microdialysis of active MTPs in the upper trapezius muscle demonstrated that they present a unique biochemical environment when compared to latent MTPs and normal muscle tissue [4]; they are more acidic, with higher levels of inflammatory mediators such as neuropeptides, catecholamines, vasoactive amines, and proinflammatory cytokines. These mediators are associated with states of persistent pain, inflammation, and neuronal sensitization phenomena [5].
MTPs can be inactivated by noninvasive physiotherapy measures, such as applying a cold spray, followed by muscle stretching maneuvers or transcutaneous electrical stimulation. Minimally invasive treatments for MTPs include injections with local anesthetics, corticosteroids, or botulinum toxin. Accurate injections on trigger points are vital to help deactivate them [6]. However, the effectiveness of infiltration techniques in MTPs inactivation seems to depend less on the substance injected and more on the actual puncture produced by the needle used. Comparison of local anesthetic injection and dry needling (DN) showed that both were effective in reducing levels of myofascial pain, as well as increasing cervical mobility and decreasing levels of depressive symptoms in patients with cervicalgia [7].

The effectiveness of DN is probably in the mechanical disturbance of the integrity of dysfunctional motor endplates [4]. DN may also activate the descending inhibitory system of pain and cause local deactivation of MTPs [5]. In addition, after DN, concentrations of substances related to neuroinflammation, such as Substance P (SP) and Calcitonin Gene-Related Peptide (CGRP) in active MTPs were significantly reduced, which clinically corresponded to the immediate decrease in pain and local sensitivity and an increased pressure pain threshold measured by algometry [4].

When the needle is inserted superficially into the tissue covering the myofascial trigger point (MTP), the technique is called superficial DN. When the MTP is touched directly by the needle, it is called deep DN (DDN). Ideally, both techniques use acupuncture needles exclusively, since their extremely low gauge produces minimal tissue damage. It has been shown that the deep DN method is more effective than the superficial method in treating the pain associated with MTP [8]. In patients with TMD, the effectiveness of deep DN was assessed in the treatment of different masticatory muscle groups. The effect of deep DN on active MTPs in extraorally accessible masticatory muscles, masseter and temporalis, has been shown to produce significant increases in pressure pain thresholds and an also significant decrease in pain intensity [9,10].

Controlled clinical trials are considered the “gold standard” for assessing the efficacy and safety of a therapeutic intervention and are the essential instrument of evidence-based clinical practice in the health field [11]. In order to increase accuracy in identifying differences between therapeutic modalities, for the possibility of their existence to be beyond chance, a prior estimate of the appropriate number of participants to be included in the intended trial is required [12,13]. On the other hand, given the implications of controlled clinical trials in terms of investment of time and resources, recruiting a sample size no larger than appropriated to demonstrate the expected differences becomes imperative [14]. Including an unjustifiably large number of participants may also be considered unethical, for exposing more participants to procedures potentially ineffective or with significant adverse effects, as well as depriving additional control group individuals of the potential beneficial effects of the therapy tested [15].

To calculate the appropriate size of a sample, initially, regardless of the adopted study design, its objectives and the primary outcomes to be investigated have to be defined. The choice of the expected outcomes for the study is fundamental and cannot be changed during the course of the study, since there are specific methods for the sample size calculation for each type of measure considered. The minimum difference that the investigator intends to detect between the groups studied represents the “effect size” in the calculation of the sample size [16]. Thus, if the researcher alters the choice of results after the start of the study, the statistical significance and the resulting inferences become inadequate [17].

Relevant data for calculating the sample size of a clinical trial can be obtained from results from previous studies with similar designs, such as the differences found in the mean and standard deviation of pain thresholds by pressure algometry in different muscle groups after the use of a minimally invasive DN therapeutic protocol. Such estimates should ideally be obtained through systematic reviews and/or meta-analyses aiming to identify effects that are not only statistically significant, but clinically as well.

Kietrys et al. [18] conducted a systematic literature review and meta-analysis to evaluate the effectiveness of DN in the treatment of upper-quarter myofascial pain. Three of the four studies included in the meta-analysis found a broad therapeutic effect of DN when compared to placebo needling (sham) or controls. Subsequently, Morihisa et al. [19] systematically reviewed the literature to evaluate and produce an overview for the use of DN as an intervention for lower-quarter MTP inactivation in patients with different orthopedic conditions. The results from the included studies also suggested that DN is an effective intervention in reducing the pain associated with the presence of lower-quarter MTP, at least in the short-term.

At present, there is no known publication of systematic reviews of controlled clinical trials investigating the effectiveness of DN as an intervention for MTP inactivation in patients with masticatory myofascial pain. Only one recent study has systematically reviewed
clinical trials published up to 2015 to determine the effectiveness of acupuncture, including but not exclusively DN, in the treatment of myofascial pain in TMD patients [20].

Pilot studies can also be employed to support the researcher when there is insufficient information available in the literature. A pilot study not only helps in estimating sample size but also tests the feasibility of the study [21]. The pilot study is a small-scale trial run as a pre-test, preceding a larger proposed clinical trial. It allows preliminary testing of hypotheses and can suggest some change or withdrawal of old hypotheses, or even the development of new hypotheses, so that they can be tested more precisely. The pilot study almost always provides sufficient data for the researcher to decide whether or not to proceed with the main study.

Thus, the objective of the present study was to evaluate the short-term effectiveness of DDN, when compared to sham DN, in the reduction of pressure pain thresholds measured by algometry in patients with chronic masticatory myofascial pain, based on a minimum selected sample size. For this purpose, a systematic review of the literature was conducted to identify previously published controlled clinical trials evaluating the same primary outcome. The means and standard deviations retrieved from the results of the selected studies were used to calculate the sample size required for this preliminary clinical trial.

**Materials and methods**

Although the most common mode of controlled clinical trial is the conventional paired-group design, “split-face” designs may also be employed. In the paired-group design, the participants are randomly allocated to the intervention and control groups; in the “split-face” design, each intervention is randomly allocated to a different side of the face of the same individual. An advantage of this study model is the small sample size required, compared to the paired-group design [22]. This is due to the fact that each patient acts as his/her own control. In this way, much of the inter-individual variability is removed, resulting in increased power of the study and, consequently, a decrease in the number of participants required compared to studies in which each participant receives only one intervention. It is estimated that the sample size required for a “split-face” clinical trial is half that required for a paired-group clinical trial when all other study parameters are equivalent [23].

Thus, a double-blind, cross-over, and “split-face” clinical trial was conducted involving patients who appeared on an ongoing basis for treatment of chronic pain in the temporomandibular region at the TMD and Orofacial Pain Outpatient Teaching Clinic at the Petrópolis School of Medicine, in the State of Rio de Janeiro, Brazil. All patients received detailed information about the research and signed a free and informed consent form before any procedure was performed. This study was approved by the Ethics and Scientific Research Committee of the Petrópolis School of Medicine, under protocol no. 0022.0.315.000–07.

The appropriate sample size for this trial was calculated from the results retrieved from a systematic review that followed the guide “Preferred Reporting Items for Systematic Reviews and Meta-Analyses” [24]. Articles were identified through a literature search conducted using the following databases: (1) PubMed; (2) Latin American and Caribbean Health Sciences (LILACS); (3) Scientific Electronic Library Online (SciELO); and (4) The Cochrane Library.

The terms used for the search in all databases cited above were: (dry needling OR acupuncture OR intramuscular stimulation) AND (trigger point OR myofascial pain). The selection of search terms was based on the publication by Dunning et al. [25], stating that many scientific articles also used the terms “intramuscular stimulation” and “acupuncture” to describe the intervention by dry needling. The inclusion of the search term “acupuncture” produced a large number of results. However, studies using only traditional acupuncture, which rely on the principles of Traditional Chinese Medicine as the method for needle insertion, were excluded from the evaluation.

The results of the search were limited to: (1) clinical trials or systematic reviews; (2) texts in English, Portuguese, or Spanish; (3) use of dry needling to inactivate myofascial trigger points in the masticatory extraoral muscles for the control of chronic muscular TMD; (4) use of dry needling compared to another intervention or the absence of intervention; and (5) primary outcomes assessed by the reduction of pressure pain thresholds measured by algometry. Only randomized clinical trials (RCTs) were considered for inclusion; however, the list of references of systematic reviews were explored in search of relevant studies related to the topic in question. To maximize the number of search results, no date limit was set.

Two authors independently conducted the search using the search terms listed above. These authors compiled a list of studies to be evaluated for eligibility based on their title and abstract. After reading the full text of the articles selected, the reviewers documented the reasons for exclusion. Studies were excluded that: (1) used traditional acupuncture as the method for applying the needles; (2) included treatment by injections, such as...
platelet-rich plasma or botulinum toxin; (3) treated regions of the body other than the temporomandibular joints; or (4) were not RCTs. Discrepancies in the studies selected to be included and/or excluded were discussed between the two reviewers until consensus on the decision was reached.

Each of the studies was reviewed independently by the same two reviewers, and discrepancies were resolved by consensus. Data on the methods and results of the studies were collected independently by the two reviewers. The information items extracted in relation to the method were as follows: (1) study design; (2) sample size; (3) male/female and control/experimental group ratio; (4) description of the dry needling technique; (5) duration and frequency of treatment in the experimental group; (6) description of the intervention for the control group; and (7) prognostic factors for the experimental and control groups.

Although it is possible to estimate the size of the sample by taking into account all available measures of results, the increase in the number of expected results inevitably leads to an increase in the number of individuals to be included, often making the research very difficult to conduct. In the literature, various outcome modalities can be found for a particular study design, and it is the responsibility of the principal investigator to determine the expected primary outcome of the study.

The primary outcome adopted in this study was the pressure pain threshold measured by algometry.

Thus, the result measurements had to include, but were not limited to, the pressure pain threshold measured by algometry. In considering the measurement of results, the following information was extracted: (1) means and standard deviations of the groups at the start and in each follow-up period; (2) statistical analysis of the difference between groups. The measurement results were analyzed to determine if the experimental group was considered superior, equal, or inferior to the control group.

A total of 25 studies were considered for inclusion based on title and abstract. After the full text review of each selected article, only 2 studies met the inclusion criteria (Tables 1 and 2). Each of the 2 studies selected for inclusion was a randomized clinical trial, where pain threshold measurements taken by pressure algometry were the expected primary outcome. Application of dry needling included “deep insertion,” while control interventions included “sham” dry needling. The duration and frequency of treatment ranged from a single session to two sessions with a one-week interval.

The formula for calculating the appropriate size of a sample should be chosen based on the type of study, the confidence interval, and the statistical power desired. A 95% confidence interval and statistical

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**Table 1. Information on the characteristics of the included studies.**

<table>
<thead>
<tr>
<th>Authors, Year of Publication</th>
<th>Study design</th>
<th>Sample size</th>
<th>Male-Female ratio</th>
<th>Control group – experimental group</th>
<th>Description of the dry needling technique</th>
<th>Duration and frequency of treatment in the experimental group</th>
<th>Description of the intervention for the control group</th>
<th>Prognostic factors for the experimental and control groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fernández-Carnero et al. [9]</td>
<td>Prospective</td>
<td>12</td>
<td>0:12</td>
<td>6:6</td>
<td>DDN</td>
<td>2 sessions at an interval of 1 week</td>
<td>SDN</td>
<td>PPT masseter muscle and mandibular condyle (kPa) Active mouth opening (degrees) Mean Allographic Measure (kg/cm²) Unassisted jaw opening without pain (mm)</td>
</tr>
<tr>
<td>Diraçoğlu et al. [10]</td>
<td>Prospective</td>
<td>52</td>
<td>7:45</td>
<td>26:26</td>
<td>DDN</td>
<td>1 session</td>
<td>SDN</td>
<td></td>
</tr>
</tbody>
</table>

PPT: Pressure pain threshold; DDN: Deep dry needling; SDN: Surface dry needling.

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**Table 2. Results found in included studies and employed in the calculation of sample size of the present study.**

<table>
<thead>
<tr>
<th>Authors, Year of Publication</th>
<th>Research parameters</th>
<th>Pre-intervention</th>
<th>Post-intervention</th>
<th>Mean difference</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fernández-Carnero et al., 2010</td>
<td>PPT masseter muscle (kPa)</td>
<td>98.5 (81.1–115.7)</td>
<td>176.5 (157.2–195.9)</td>
<td>79.1 (57.4–98.8)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Dry needling</td>
<td>108.7 (91.4–126.1)</td>
<td>100.0 (80.6–119.4)</td>
<td>-8.0 (–21.8–4.4)</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Sham dry needling</td>
<td>91.5 (70.6–112.3)</td>
<td>182.0 (159.9–204.1)</td>
<td>98.9 (78.6–125.6)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>PPT mandibular condyle (kPa)</td>
<td>113.3 (95.5–131.1)</td>
<td>104.9 (86.1–123.7)</td>
<td>-7.4 (–20.7–4.0)</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Dry needling</td>
<td>30.9 (26.2–35.5)</td>
<td>41.5 (35.2–47.7)</td>
<td>34.3 (7.7–13.5)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Sham dry needling</td>
<td>36.2 (29.8–42.2)</td>
<td>36.1 (29.8–42.3)</td>
<td>-0.2 (3.0–2.8)</td>
<td>*</td>
</tr>
</tbody>
</table>

*Not informed; PPT: Pressure pain threshold.*
power of 80% were chosen, based on the standard adopted for most studies in the health field [26].

The formula used to calculate the sample size is described below:

\[ N = (Z\alpha + Z\beta)^2 \times \frac{(V_1 + V_0)}{(M_1 - M_0)^2} \]

where:

- \( N \) – sample size;
- \( Z\alpha \) – value for alpha error (5%) = 1.96;
- \( Z\beta \) – value for beta error (20%) = 0.84;
- \( V_1 \) – patient group expected variance;
- \( V_0 \) – control group expected variance;
- \( M_1 \) – patient group expected mean;
- \( M_0 \) – control group expected mean.

The studies selected and used as the basis for calculating the ideal sample size of the present study are described below:

Study 1: Short-Term Effects of Dry Needling of Active Myofascial Trigger Points in the Masseter Muscle in Patients With Temporomandibular Disorders [9].

\[ N = \frac{(1.96 + 0.84)^2 \times (428.4 + 171.6)}{(78.1 + 8.7)^2} = \]
\[ N = \frac{(2.8)^2 \times (600)}{(7534.2)} = \]
\[ N = 7.84 \times \frac{(600)}{(7534.2)} = \]
\[ N = 0.6 \text{ patients}/2 = 0.3 \]

Study 2: Effectiveness of dry needling for the treatment of temporomandibular myofascial pain: A double-blind, randomized, placebo-controlled study [10].

\[ N = \frac{(1.96 + 0.84)^2 \times (0.324 + 0.003)}{(-0.57 + 0.06)^2} = \]
\[ N = \frac{(2.8)^2 \times (0.327)}{(0.26^2)} = \]
\[ N = 7.84 \times \frac{(0.327)}{(0.26)} = \]
\[ N = 9.8 \text{ patients}/2 = 4.9 \]

Therefore, the sample size calculated for the present study was limited to 5 patients, who acted as their own controls.

For the clinical trial conducted, the inclusion criteria were: (1) diagnosis of myofascial pain according to the DC/TMD criteria; (2) pain on palpation of myofascial trigger points involving the masseter muscle bilaterally; (3) symptom duration of at least 3 months; and (4) age between 18 and 65 years. Exclusion criteria were: (1) trauma in the face and cervical region; (2) gestation; (3) rheumatoid arthritis; (4) polymyalgia rheumatica or temporal arteritis; (5) odontogenic infection; (6) use of analgesics in the past 7 days; (7) polymyositis or dermatomyositis; (8) systemic arterial hypertension; (9) cardiopathies; (10) coagulation disorders; (11) use of anticoagulants; or (12) having received treatment with acupuncture, dry needling, or physiotherapy in the 6 months prior to treatment.

Each patient served in both the control group and the experimental group since they received DDN treatment in the MTPs on one randomly chosen side while receiving superficial DN outside the MTPs on the other side (sham). The sham dry needling looked exactly like real dry needling except it penetrated only a few millimeters of the skin without effectively reaching the trigger point. In this way, each patient acted as his/her own control. At a second point in the study, after assessing the results of the first phase, the experimentally-needled side and the control side were reversed and the new results assessed.

An electronic algometer (Instrutherm, mod. DD-020, São Paulo, Brazil) was used to evaluate the pressure pain threshold at the MTPs in the masseter muscles on both sides. The authors used the calibration of kg/cm2 for the algometer. Algometry was done before and immediately after the dry needling. DDN therapy was done in three sessions at least seven days apart. After the three sessions, the MTPs that received the experimental dry needling, i.e., inside the MTP, received placebo dry needling, i.e., outside the MTP, and vice versa. Then, another sequence of three sessions was carried out, also at least seven days apart.

Immediately afterwards, the most painful points in the masseter muscles were identified through palpation, according to the standard clinical criteria defined by Travell and Simons [27]. In this study, any region of myofascial tissue without identifiable nodules on palpation was defined as “normal” or not involved. A site in the masseter muscle with an MTP was identified on each side in each patient. The examiner then marked “false” points outside the MTPs, but close to them, and recorded these points as “normal.” This process resulted in two locations marked on each muscle (a total of four per patient).

Pressure algometry was performed at each of the four points to determine the pressure pain threshold, i.e., the minimum amount of pressure capable of producing the sensation of pain. The patient was asked to relax, and pressure was applied through the tip of the algometry apparatus over the marks, perpendicular to the skin’s surface. Participants were instructed to say, “pain” when the sensation changed from pressure to pain. At that moment, the device was immediately withdrawn and the measured value transferred to the data collection table. Three measurements were taken with 30-s rest intervals, and the mean was calculated and used for analysis.

The DDN therapy was conducted by a different examiner from the one who did the assessment, and the former did not reveal the side selected for experimental treatment either to the patient or to the other examiners. Sterilized stainless steel needles 30 mm long and 0.25 mm gauge, with a cylindrical plastic guide (Dong Bang Acupuncture, Inc., Chungnam, Korea), were used for this therapy. The DDN procedure
began with alcohol disinfection of the skin. After identification of the MTPs via palpation, they were then compressed with the index finger or middle finger of the non-dominant hand to guide the needle insertion point. Then rapid needle insertion and withdrawal movements were performed. The simulated dry needling (placebo) looked like true dry needling, since it penetrated the skin, but only a few millimeters and outside the MTPs.

The clinical follow-up of the patients selected in this study was done by the same examiner at the time of diagnosis (initial clinical evaluation) and during the clinical follow-up period: 15, 30, 60, and 90 days after the DDN therapy. The clinical parameter assessed was the pressure pain threshold (assessed through pressure algometry of the MTPs).

**Statistical analysis**

All data were analyzed using SPSS software version 15.0 (SPSS Inc, Chicago, IL, USA). For all statistical tests, the level of significance was set at 5%. The percentage of variation of the mean value of the three consecutive measures of pressure pain threshold measured by algometry, before and after the needling procedure, was calculated. Analysis of the statistical significance of this difference was carried out using the Wilcoxon test for paired data.

The power of a statistical test corresponds to the probability of correctly rejecting the null hypothesis [28] and depends on three basic aspects: expected effect size, desired significance level, and sample size [29]. The level of significance corresponds to the risk of rejecting the null hypothesis erroneously, i.e., the absence of a real difference in the parameter studied, between the two groups.

Although it dominates the scientific literature, this parameter does not validate any assertion about the mathematical probability of a given hypothesis [30]. Although the p-value gives the statistical probability of the observed differences having arisen only by chance, its role in the statistical significance of the results obtained can only be properly considered when its function is previously supported explicitly by a theory, i.e., when the hypothesis is clearly stated before the data are obtained [31]. Significance level is also criticized for its arbitrariness, because through its use, the researcher erroneously passes from a continuum of uncertainty to a dichotomous decision to reject a hypothesis or not. In addition, the significance level does not indicate the clinical importance of the results obtained [32].

Significance level is affected by the characteristics of the study, with sample size being the main determinant [33]. As such, there is greater likelihood of obtaining a significant p-value with large sample sizes and, conversely, in small-sized samples, the p-value may not be significant within the given significance parameters even though the size of the effect might be large [34].

Effect size corresponds to a simple method for quantifying the size of the difference between two groups and can be applied to any measure of results but is particularly valuable in assessing the effectiveness of a particular intervention when compared to the other. In addition to having the advantage of not depending on sample size, it also provides information on the meaning of the results, consisting of a common unit of measure for comparing results from different studies [34]. Since, most of the time, data on the studied population are not available, effect size more commonly refers to the estimation of the magnitude of the relationship between variables to the effect of one variable on another or to the difference between two samples [35].

In the modality of effect size based on the values of means and standard deviations, effect size expresses the magnitude of the difference between the groups studied, in relation to a given characteristic variable, but for this it is essential that the distribution of the values from the sample follows a normal pattern [36]. The nonparametric tests for the calculation of effect size between two groups of observations do not depend on the mean, depending only on a concept of dominance. This approach considers the ordinal properties of the data rather than the interval properties.

Effect size was calculated using the Cliff’s Delta statistical test for non-normal distributions [37].

The Cliff’s Delta statistic can be obtained from the following equation:

\[
\Delta = \frac{\sum_{x1} (x1 > x2) - \sum_{x1} (x1 < x2)}{n1.n2}
\]

Where \(\sum_{x1} (x1 > x2)\) and \(\sum_{x1} (x1 < x2)\) correspond, respectively, to the number of times each Group 1 score (experimental treatment) exceeds that of Group 2 (placebo treatment) and vice versa; while \(n1\) and \(n2\) correspond to the sample sizes of the respective groups.

Thus, it is estimated that a selected value from one of the groups is greater than a selected value from the other group, minus the inverse probability. Cliff [37] interprets this as a measure of dominance, a concept that refers to the degree of overlap between two distributions. All possible values of the Cliff’s Delta measurements are in the closed range from -1 to +1. An effect size of +1.0 or -1.0 indicates the absence of overlap between the two groups, while the value of 0.0 indicates that the group distributions overlap completely. When a significant p-value is obtained, the associated effect size should be close to +1.0 or -1.0,
Results

The pressure pain thresholds measured by algometry, before and after three sessions of unilateral therapy, experimental and placebo, of DDN on MTPs in the masseter of the 5 patients of the sample, as well as the percentage change in these measurements were demonstrated in Table 3. All 5 patients included were women, ranging in age from 33 to 80 years, with a mean age of 49.6 years ± 19.2.

DDN increased, in a statistically significant manner ($p = 0.04$), the pressure pain threshold measured by algometry in the MTPs in the masseter on the experimental side (44.60% ± 16.32), when compared to the placebo procedure on the control side (−5.5% ± 22.85).

For the present study, the effect size was calculated as follows:

$$\text{Delta} = 25(x_1 \leq x_2) - 0(x_1 \geq x_2) = 25/25 = 1$$

5X5

Discussion

Fernández-Carnero et al. [9] assessed the effectiveness of DDN in the inactivation of active MTPs in the masseter muscle in a group of 12 women. Positive results were obtained in the increase of the pressure pain threshold measured using an algometer [9]. Similarly, the present study demonstrated that DDN of active MTPs in the masseter muscle promoted a statistically significant increase ($p = 0.04$) in the pressure pain threshold compared to placebo DN on the opposite side of the same patient.

Although DDN has been investigated regarding its effectiveness in MTP inactivation, both local and satellite [38], and in reducing the clinical parameters of chronic myofascial pain [39] in different muscles of the cervical region, such as the trapezius [7] and infraspinatus [40], studies on the effectiveness of DDN on MTPs in masticatory muscles are scarce. In the present study, the final value of the effect size was +1, i.e., absolute, according to Cliff's classification [37]. These results support the hypothesis of DDN effectiveness in the inactivation of active MTPs, possibly related to the signs and symptoms present in patients with chronic masticatory myofascial pain. However, the observed effects were assessed only in the short-term, and longitudinal monitoring of these patients over the long-term should be explored in future studies.

The mechanisms of MTP inactivation by DDN have not yet been fully elucidated. Pain intensity and pressure pain threshold are highly correlated with the levels of electrical activity in the MTP region [41], with DDN significantly inhibiting spontaneous electrical activity in the MTPs in rabbits [42]. Likewise, the reduction in levels of algogenic and proinflammatory substances (neuropeptides, catecholamines, and proinflammatory cytokines) in active MTPs, following the induction of multiple local contraction responses during DDN, may also be involved in pain reduction and the increase of its threshold [4]. Regardless of peripheral mechanisms, the inactivation of active MTPs through DDN has also been shown to involve supraspinal pain control mechanisms, related to both antinociception and pain relief in the MTPs [43]. Thus, it is possible that both the peripheral and central mechanisms are involved in the therapeutic effects of DDN on the active MTPs and in the improvement of the clinical parameters of patients with masticatory myofascial pain.

Apparently, the mechanical rupture of the tissue caused by needle insertion constitutes part of the therapeutic effect, possibly related to the depolarization of the membrane of motor efferent nerve fibers caused by the release of intracellular potassium and interruption of the central feedback mechanism [44]. The presence of a neurological mechanism seems reasonable, as pain relief after performing DDN often occurs in a few seconds, as observed in the present study.

Thus, the efficacy of infiltrative techniques in the inactivation of active MTPs seems to depend less on the substance injected and rather on the mechanical effect produced by the insertion of the needle. The comparison of local anesthetic injection and dry needling demonstrated that both were effective in reducing

Table 3. Pressure pain threshold measured in kgf through pressure algometry before and after DDN therapy.

<table>
<thead>
<tr>
<th>Patient 01</th>
<th>Beginning of therapy</th>
<th>After 3 needling sessions</th>
<th>Changes in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.44</td>
<td>0.46</td>
<td>4.5%</td>
</tr>
<tr>
<td>Dry needling</td>
<td>0.44</td>
<td>0.77</td>
<td>75%</td>
</tr>
<tr>
<td>Patient 02</td>
<td>Control</td>
<td>0.47</td>
<td>0.49</td>
</tr>
<tr>
<td>Dry needling</td>
<td>0.43</td>
<td>0.66</td>
<td>93.4%</td>
</tr>
<tr>
<td>Patient 03</td>
<td>Control</td>
<td>0.55</td>
<td>0.38</td>
</tr>
<tr>
<td>Dry needling</td>
<td>0.45</td>
<td>0.68</td>
<td>51.1%</td>
</tr>
<tr>
<td>Patient 04</td>
<td>Control</td>
<td>0.53</td>
<td>0.57</td>
</tr>
<tr>
<td>Dry needling</td>
<td>0.67</td>
<td>0.82</td>
<td>22.3%</td>
</tr>
<tr>
<td>Patient 05</td>
<td>Control</td>
<td>0.61</td>
<td>0.53</td>
</tr>
<tr>
<td>Dry needling</td>
<td>0.66</td>
<td>0.80</td>
<td>21.2%</td>
</tr>
</tbody>
</table>

Kgf: Kilogram-force; DDN: Deep dry needling.
levels of myofascial pain [7]. In the present study, intramuscular puncture was not used to inject local anesthetics, corticosteroids, or botulinum toxin, substances commonly used. Thus, the myotoxic effects of infiltration with these drugs were avoided [45].

Thus, the MTP DDN technique seems to be a safe and effective method, at least in the short-term, in the treatment of patients with chronic masticatory myofascial pain. However, although the intervention therapy has demonstrated a strong effect size in increasing PPT levels, this isolated outcome is not directly comparable with more general outcomes, such as the intensity and severity of the pain experienced or the patient’s perception of treatment efficacy and quality of life. The “split face” design prevents the study from drawing these conclusions because as both treatments, experimental and control, were performed in the same patients at the same time, there is no control group of patients to be compared. Another limitation of the present study is that, since there is dimensioning of effect size and a relatively small sample, the need for further studies should be noted.

Conclusion

Patients with chronic masticatory myofascial pain treated with DDN of MTPs show an increased pressure pain threshold, as measured by algometry, on the experimental side when compared to a placebo procedure performed on the opposite side. The calculated value for the size of this effect was considered absolute.

Disclosure statement

The authors have no conflict of interest to declare.

References


