Randomized Trial

Effectiveness of Dry Needling with Percutaneous Electrical Nerve Stimulation of High Frequency Versus Low Frequency in Patients with Myofascial Neck Pain

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Background: Percutaneous nerve electrical stimulation is a novel treatment modality for the management of acute and chronic myofascial pain syndrome.

Objectives: To compare the effectiveness of dry needling combined with percutaneous electrical nerve stimulation of low frequency versus high frequency, in patients with chronic myofascial neck pain.

Study Design: Randomized, single-blind trial.

Setting: Laboratory in an academic institution.

Methods: A total of 40 volunteer patients with chronic neck pain were randomly divided into 2 groups. All patients initially received deep dry needling in a myofascial trigger point of the upper trapezius. Then, one group received high frequency percutaneous electrical nerve stimulation while the other group received low frequency percutaneous electrical nerve stimulation. The primary outcomes were the visual analog scale and the pressure pain threshold, while Neck Disability Index and Kinesiophobia were secondary outcomes.

Results: We detected significant improvements in the visual analog scale score in both groups without differences between them. We did not observe significantly different statistics in either group during the evaluation of data on pressure pain threshold.

Limitations: Limitations of the study include (1) heterogeneity of the sample in relation to gender, with more women, (2) the small sample size (40 patients), (3) the absence of placebo group, and (4) the fact that the treatment is focused exclusively on the upper trapezium myofascial trigger point. .

Conclusions: Low and high frequency percutaneous electrical nerve stimulation combined with deep dry needling showed similar effects, since no differences between groups were observed on any of the outcome measures. High and low frequency of percutaneous electrical nerve stimulation generates changes on pain intensity and disability, but not on pressure pain threshold or fear of movement.

Key words: Neck pain, disability, trigger points, TENS, PENS, dry needling, physiotherapy, neck muscles

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Cervical pain is one of the most frequent causes of medical consultation and it is currently considered a public health problem (1). Worldwide, this ailment affects 15% – 25% of the adult population and can increase up to 50% in people over 65 years of age (2). The Spanish National Health Survey

2011 – 2012 found that one in 6 adults (over the age of 15) claims to have some episode of cervical pain (3). The direct cost of cervical pain can reach 12% of the total health cost, including diagnostic tests, pharmacological expenses, and medical consultations. In Spain, referrals to physiotherapy services for cervical pain make up more than 10% of all health demands (4).

Factors associated with chronic neck pain include the decrease of quality of life and the increase of neck disability (5,6); psychosocial factors such as kinesiophobia, catastrophizing, and depression (6,7); as well as an increase of sensitivity to pain or mechanical stimulus when compared with asymptomatic patients (8).

In addition, myofascial trigger points are considered a common source of pain in chronic nonspecific neck pain (9).

Treatments to address neck pain of myofascial origin include pharmacological and nonpharmacological measures. The most commonly used drugs are nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, anticonvulsants, and opioids (10). Within the nonpharmacological treatment, physiotherapy is frequently used. It can be approached with different conservative techniques of manual therapy and/or various physical agents (11,12). Electrotherapy includes transcutaneous electrical nerve stimulation (TENS), a noninvasive analgesic technique used to reduce both acute and chronic pain (13). There are different types of TENS, described according to their characteristics, such as high and low frequency TENS (13,14). In addition, invasive treatment techniques that include infiltration, acupuncture, dry needling, or electroacupuncture are being used to relieve myofascial pain (15). Deep dry needling consists of the insertion of a needle in the active trigger point, by means of which an analgesic effect is obtained through the mechanical stimulus and the neurophysiological effect associated with the introduction of the needle (16).

Today there is a novel treatment modality, known as percutaneous electrical nerve stimulation (PENS), which is considered a form of electroacupuncture in which an electric current is applied through needles conveniently placed in different body points (17). It is a variant of dry needling in which the needle is used as an electrode for the application of the current. PENS has been shown to be an effective method for the relief of pain associated with various conditions such as chronic low back pain (17-19), headache (20,21), neuropathic pain (22,23), or postoperative pain (24). However, the effectiveness of PENS in the treatment of chronic myofascial neck pain has been sparsely investigated (25), as well as the influence of the electric current frequency parameters on its effectiveness. Previous research suggested that pain-modulating mechanisms are influenced by frequency-specific opioid inhibition (26).

The main objective of this study is to test the effects of deep dry needling combined with high versus low frequency PENS in the short term, by means of pain intensity. As secondary objectives, we tested the effectiveness of deep dry needling combined with high versus low frequency PENS in the short term for mechanical hyperalgesia, disability, and fear of movement.

Methods

Study Design, Ethical Considerations, and Trial Registry

This study is a randomized controlled clinical trial conducted in accordance with the CONSORT statement (27). Forty-two patients were blinded to group assignment, and the assessor was blinded to allocation. Randomization into 2 groups, low frequency (LF) PENS group (LF-PENS), and high frequency (HF) PENS group (HF-PENS), was performed using a computer generated random-sequence table with a 2-balanced block design (GraphPad Software, Inc., La Jolla, CA, USA). A member of the research team who was not involved in the assessment or treatment of the patients oversaw the randomization and maintenance of the list. All of the procedures used in this study were planned according to the ethical principles of the Declaration of Helsinki and were approved by the Ethics Committee of Centro Superior de Estudios Universitarios La Salle (registration number: CSEULS-PI-115/2016) and the study was carried out at La Salle University, Madrid. The trial was registered in the US National Institutes of Health Clinical Trials Registry with the registration number NCT03401905.

Patients

Patients with chronic neck pain were enrolled from Centro Superior de Estudios Universitarios La Salle, between February and April 2018. Patients were contacted via mail and leaflets. Forty-two patients were randomized and one patient in each group was lost during the follow-up, thus 20 patients per group were analyzed.

The inclusion criteria were aged 18 – 65 years; neck pain perceived in the posterior region of the cervical spine, from the superior nuchal line to the first thoracic spinous process with more than 12 weeks of evolution

and without radicular symptoms radiating to the head, trunk, and/or the upper limbs; the presence of active trigger points in the trapezius muscle, according to Simons' criteria (28) and the ability to understand, write, and speak Spanish fluently.

They were excluded if they presented: development of systemic or degenerative diseases; pain in any area of the lower back and/or the head in the last 9 months; neck pain associated with whiplash injuries; medical red flag history (i.e., tumor, fracture, metabolic diseases, rheumatoid arthritis, osteoporosis); neck pain with cervical radiculopathy; neck pain associated with externalized cervical disc herniation, fibromyalgia syndrome, previous neck surgery; neck pain accompanied by vertigo caused by vertebrobasilar insufficiency or accompanied by noncervicogenic headaches due to a traumatic event in the past 12 months; and history of neck or face pain in the last 6 months.

Measures

Primary Outcome Measurements

Visual Analog Scale

As a primary outcome measurement, visual analog scale (VAS) was used to measure pain intensity, as this instrument has been shown to be valid (Spearman's rho values varied from 0.76 to 0.84) and reliable (Spearman's rho values varied from 0.60 to 0.77) for measuring pain intensity in patients with chronic musculoskeletal pain (29). This scale consisted of a line 10 cm long. The point 0 cm corresponds to "no pain" and the point 10 cm corresponds to "the worst pain imaginable." The patients placed a vertical mark at the level corresponding to their pain. Consensus recommendations indicated that a decrease of 2 points over 10 or a 30% reduction in pain intensity on VAS are considered moderately clinically meaningful differences (MCID) (30).

Pressure Pain Threshold

The pressure pain threshold (PPT) is defined as the minimum amount of pressure that can cause pain, evaluated using an algometer. Three measurements were made with a digital algometer (Wagner Instruments, Greenwich, CT, USA), which reported the measurements in Kg/cm^2, leaving intervals of 35 seconds between each of them and making an average of the 3 measurements in the upper trapezius. This tool has shown to be a valid (Pearson's correlation coefficient of 0.99) and reliable (Pearson's correlation coefficient of 0.99) for the assessment of PPT considering readings from a force plate and rate of force application, respectively (31).

Secondary Outcome Measurements

Neck Disability

The Neck Disability Index (NDI) was used to measure cervical disability. The Spanish version of the NDI showed a very good internal consistency (α Cronbach varied from 0.937 to 0.944), excellent test-retest reliability (intraclass correlation coefficient of 0.978), and adequate construct validity (correlation with the VAS from 0.643 to 0.743) for the measurement and self-assessment of cervical disability (32). This questionnaire is composed of 10 questions related to the ability to function in many activities of daily living and presents an acceptable reliability. For the measurement of the cervical disability index, the questionnaire was completed at the beginning and at the end of the study. A difference of at least 5 points with respect to the initial score is necessary to consider a minimum detectable change (MDC).

Fear of Movement

The fear or movement and (re)injury was evaluated using the Tampa Scale for Kinesiophobia (TSK-11) (33). This is a questionnaire of 11 items and the patients indicate their degree of agreement/disagreement with each of the statements it contains, using a scale from 1 (total disagreement) to 4 (total agreement). This questionnaire was also completed both at the beginning and at the end of the study. The Spanish version of the TSK-11 has shown acceptable psychometric properties showing a good internal consistency (Cronbach's α of 0.78) and test-retest reliability (intraclass correlation coefficient of 0.82) (34-37).

Interventions

Both groups received a total of 2 PENS interventions in an active myofascial trigger (MTrP) of the trapezius muscle, once a week for 2 weeks. For this purpose, the area was first disinfected and dry needling on the MTrP of the upper trapezius was performed until 2 local twitch responses (LTRs) were obtained. Then, the needle was held so that it would later become the negative electrode. A TENS device (Model TENSMED 931, Enraf-Nonius B.V.) was used with the needle as a negative electrode and an adhesive electrode, attached to the positive pole, placed one centimeter away from

it. Dry needling was carried out using the method described by Hong et al (38), in which insertions were made with an acupuncture needle (0.32 × 40 mm, Suzhou-Huanqiu Acupuncture Medical Appliance Co. Suzhou, Jiangsu, China). In each of the interventions, the patient was told to indicate whether the intensity was well tolerated or painful. The elicitation of LTR is thought to be related to greater clinical effects of the technique (39,40).

The patients in the LF-PENS group received an intervention in which PENS was applied for 15 minutes with low frequency parameters (2 Hz) and a pulse width of 120 μs. The HF-PENS group received an intervention in which PENS applied for 15 minutes with high frequency parameters (120 Hz) and a pulse width of 200 μs. After 15 minutes of PENS in both groups, the needle was removed and a compression was applied for 90 seconds. Once the compression was carried out, the technique was concluded.

Any adverse effect that may result from the intervention was recorded by the therapist who applied the intervention.

Procedure

Once the patient had signed the informed consent, VAS and PPT variables were measured during the 2 treatment sessions; before and after the intervention. In the third session, only a final evaluation of both primary and secondary variables was performed. After the first session, a follow-up was carried out at one week (VAS and PPT) and at one month (VAS, PPT, NDI, and TSK-11). Measurements of VAS and PPT were always performed by the same assessor, while measurements of NDI, TSK-11, and treatment were performed by different assessors. To summarize, VAS and PPT were measured according to 5 follow-up periods: T1 – baseline at first day; T2 – immediately post-intervention at first day; T3 – baseline at first week; T4 – immediately post-intervention at first week; and T5 – 1 month after intervention. NDI and TSK-11 were measured according to 2 follow-up periods: T1 – baseline at 1st day; and T5 – 1 month after intervention. The duration of the treatment and its follow-up from the first session to the third and final session was one month.

Sample Size

To determine the sample size, the VAS was chosen as the primary outcome measure. Through a preliminary study the effect size f was calculated to be 0.25. Using the software G*power 3.1 (41), for analysis of variance (ANOVA) repeated measures, within-between factors, a power of 0.80, and alpha level of 0.05, was obtained for a total sample of 32 patients. Considering an abandonment rate of 20%, it was considered necessary to recruit at least 40 patients as the final sample size.

Statistical Analysis

Statistical analysis was carried out by means of the Statistical Package for the Social Sciences (SPSS) software (22.0v). Shapiro Wilk test was used to assess normality distribution showing that most variables were parametric data. Frequency (%) for categorical data and mean ± SD for parametric data were utilized to describe the study sample. Data differences between groups at baseline were compared using the Fisher exact test for gender distribution and the Student *t* test for independent samples for parametric data. Considering primary outcome measurements (VAS and PPT), a 2-way repeated-measures (ANOVA) with time (T1 – baseline at first day; T2 – immediately post-intervention at first day; T3 – baseline at first week; T4 – immediately post-intervention at first week; and T5 – one month after intervention) like within-subject factor and group (LF-PENS and HF-PENS) like between-subject factor was applied. Regarding secondary outcome measurements, a 2-way repeated-measures ANOVA with time (T1 and T5) like within-subject factor and group (LF-PENS and HF-PENS) like between-subject factor was applied. In addition, Bonferroni correction was used to test post-hoc comparisons. The Eta square coefficient (η_p^2) was calculated to determine the effect size. *P*-values and associated *F* statistics for the ANOVA analysis were reported according to Greenhouse-Geisser correction (when Mauchly test rejected the sphericity). For all statistical analyses, a *P*-value < 0.05 was considered as statistically significant.

Results

Forty-two patients were initially included in the study protocol, with 21 (17 women/4 men) randomly assigned to LF-PENS, and the remaining 21 patients (13 women/8 men) assigned to HF-PENS. During the study there were 2 losses (one patient per group) due to not completing the follow-up, so that finally 40 patients completed the sample, 20 in each group. There were not any statistically significant differences ($P < .05$) between both groups at baseline (Table 1). Flow diagram of the study is shown in Fig. 1.

Primary Outcome Measurements

Pain Intensity

Regarding VAS changes, ANOVA showed a significant effect for time ($F_{2,618}$ = 48.413; P < 0.001; η_p^2 = 0.602), but not for effects between group and time ($F_{2,618}$ = 1.963; P = 0.134; η_p^2 = 0.058) (Table 2).

Considering post-hoc analyses for LF-PENS, a pain intensity decrease was observed between T1 and T2, without showing statistically significant differences (P > 0.096). Nevertheless, at one month in relation to the first measurement, a change of almost 2 points of the VAS was observed between T1 and T5, which was considered as statistically significant (P < 0.01). For HF-PENS, statistically significant changes (P < 0.01) were observed between T1 and T5.

Pressure Pain Threshold

Regarding PPT changes, ANOVA did not show significant effects for time ($F_{3,192}$ = 1.415; P = 0.241; η_p^2 = 0.042) nor between group and time ($F_{3,192}$ = 0.497; P = 0.697; η_p^2 = 0.015) (Table 2).

Secondary Outcome Measurements

Neck Disability Index

Considering NDI changes ANOVA showed a significant effect for time ($F_{1,000}$ = 20.129; P < 0.001; η_p^2 = 0.386), but not for effects between group and time ($F_{1,000}$ = 0.609; P = 0.441; (η_p^2 = 0.019) (Table 3).

Kinesiophobia

Regarding TSK-11 changes, ANOVA did not show significant effects for time ($F_{1,000}$ = 0.018; P = 0.894; η_p^2 = 0.001) nor between group and time ($F_{1,000}$ = 0.287; P = 0.596; η_p^2 = 0.009) (Table 3).

No adverse effects were observed by the therapist who applied the intervention or reported by patients after the application of PENS.

Table 1. *Baseline patient characteristics. Values are means ± standard deviation.*

	LF PENS group n = (18)	HF PENS group n = (16)	*P* value
Age, years	54.78 ± 17.51	50. 00 ± 16.30	0.41
Gender M/F (women %)	15/3 (83.3%)	9/7 (56.2%)	0.84
PPT (kg/cm²)	4.11 ± 1.74	4.14 ± 1.29	0.96
NDI (0 to 50)	10.06 ± 6.00	10.06 ± 4.25	0.99
VAS (0 to 100 mm)	4.13 ± 1.11	4.15 ± 1.23	0.96
Psychological measures			
TSK (11 to 44)	23.39 ± 8.21	26.81 ± 10.10	0.28

Abbreviations: LF PENS, low frequency percutaneous electrical nerve stimulation; HF PENS, high frequency percutaneous electrical nerve stimulation; PPT, pressure pain threshold on trapezius muscle; VAS, visual analog scale; SD, standard deviation; NDI, neck disability index; TSK, tampa scale of kinesiophobia.

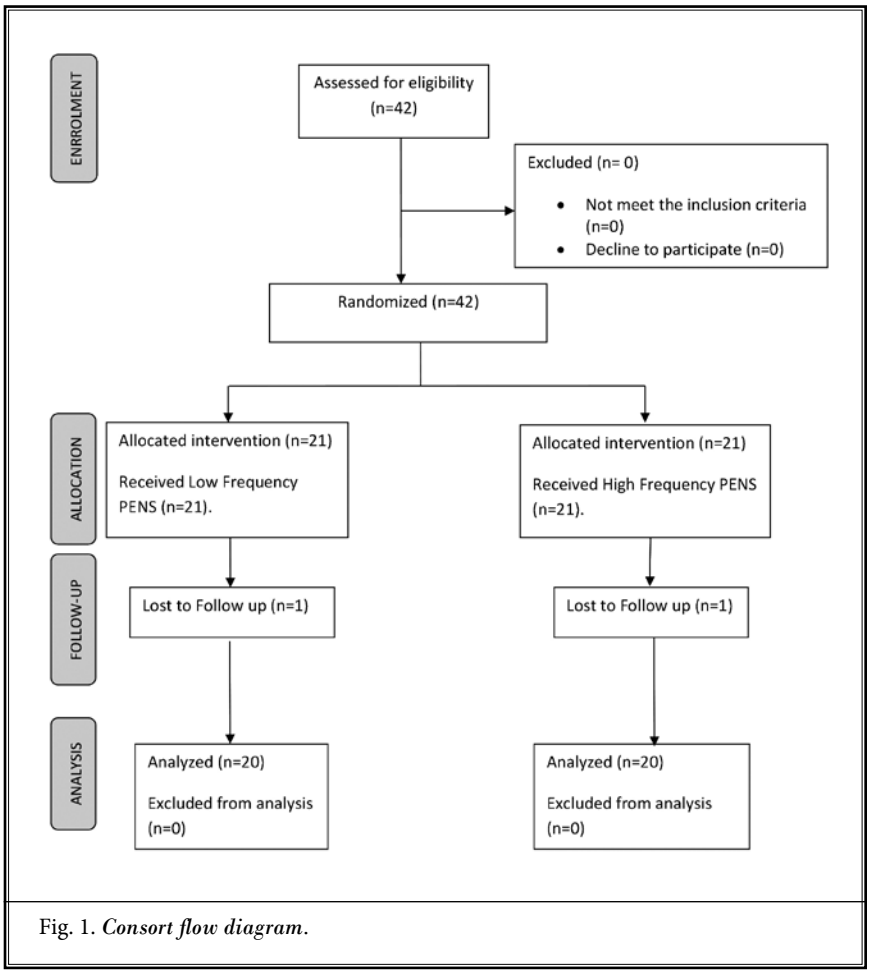

Fig. 1. *Consort flow diagram.*

Table 2. *Baseline, follow up scores, and between-group differences.*

	Baseline	Postintervention	1 week preintervention	1 week postintervention	1 month	Inta-group Differences *P* value a) Baseline vs Postintervention b) Baseline vs 1 week preintervention c) Baseline vs 1 week postintervention d) Baseline vs 1 month e) 1 week preintervention vs 1 week postintervention
Pain Intensity (VAS 0 – 10 cm)						
LF PENS	4.13 ± 1.11	3.54 ± 1.59	3.05 ± 1.14	2.49 ± 1.52	2 ± 1.75	a) 0.096 b) < 0.01* c) < 0.01* d) < 0.01* e) 0.055
HF PENS	4.14 ± 1.23	4.3 ± 1.16	3.11 ± 1.02	2.92 ± 1.1	1.96 ± 0.98	a) 1 b) < 0.01* c) < 0.01* d)< 0.01* e) 1
Pain Pressure Threshold, Trapezius (kg/cm^2)						
LF PENS	4.11 ± 1.74	3.83 ± 1.36	4.48 ± 2.09	4.31 ± 2.21	4.54 ± 2.09	a) 1.00 b) 1.00 c) 1.00 d) 1.00 e) 1.00
HF PENS	4.14 ± 1.29	4.64 ± 2.04	4.80 ± 2.01	4.98 ± 1.85	4.83 ± 1.5	a) 1.00 b) 1.00 c) 0.32 d) 0.72 e) 1.00

Abbreviations: LF PENS, low frequency percutaneous electrical nerve stimulation; HF PENS, high frequency percutaneous electrical nerve stimulation; *, $P < 0.01$

Table 3. *Characteristics of the secondary outcomes.*

	Baseline	1 month	Intra-groups Differences *P* value Baseline vs 1 month
Neck Disability Index (0-50)			
LF PENS	10.06 ± 6	7.94 ± 5.7	0.011*
HF PENS	10.06 ± 4.25	7.06 ± 4.89	0.001*
Tampa Scale of Kinesiophobia, TSK11 (11-44)			
LF PENS	23.39 ± 8.21	24.22 ± 8.4	0.629
HF PENS	26.81 ± 10.1	26.31 ± 8.62	0.784

Abbreviations: LF PENS, low frequency percutaneous electrical nerve stimulation; HF PENS, high frequency percutaneous electrical nerve stimulation; *, $P < 0.01$

Discussion

The findings of this study suggest that deep dry needling combined with low frequency PENS and deep dry needling combined with high frequency PENS produce similar immediate and short-term improvements in pain intensity and disability in patients with chronic neck pain.

There are previous studies with similar results, which support that low-frequency electropuncture generates immediate and medium-term therapeutic effects, in terms of pain reduction, in patients with cervical myofascial syndrome (42). León-Hernández et al (43) published a clinical trial in which a total of 62 patients were divided into 2 groups, performing an intervention with dry needling in the first group and electropuncture in the second. After analyzing the results obtained, they concluded, similarly to the present study, that low-frequency electropuncture improves the intensity of cervical pain and improves postneedling pain in the short-term in patients with chronic neck pain.

Aranha et al (44) presented a study in 20 women in which it was observed that the application of LF elec-

tropuncture in myofascial trigger points of the upper trapezius improves the threshold of pain at pressure and lowers the VAS score. According to our short-term results obtained in LF TENS, this data can be explained by the effect of low frequency TENS on opioid inhibitory pathways, and the stimulation of serotonin receptors on the spinal cord (45). Low frequency also activates GABA receptors, which contribute to the antihyperalgesic effect of LF TENS (46).

There are studies, such as the one presented by Maeda et al (47), which state that during intervention with HF electropuncture there is an activation of the opioid pathways, by increasing concentrations of extracellular GABA neurotransmitters in the spinal cord. It has also been demonstrated that HF also inhibits the release of activating neurotransmitters, like glutamate and aspartate, which imply a decrease of nociceptive pathways activity on the dorsal horn (48). These findings added to the gate control effect could explain the anti-hyperalgesic effect shown by the HF-PENS group.

Another finding of the effect of different frequency of TENS is that from Desantana et al (49) study, which shows that both high and low frequencies activate ventrolateral periaqueductal grey matter, meaning the activation of inhibitory descending pathways, both opioid and serotonergic.

Those findings can explain the immediate and short-term effects of both HF and LF found in our study. It also changes the classical assumption of separated effects of HF and LF, attributed to an opioid mechanism of LF and a dorsal horn mechanism of HF. Based on our findings and on those from biochemical changes carried out on animals, we can consider that both frequencies activate wider anti-hyperalgesic mechanisms, showing similar analgesic effects. This agrees with the results of this study, in which no differences were found between groups.

The results obtained in the present study indicated that there were no statistically significant changes in PPT. These data agree with the study published by León-Hernández et al (43) in which statistically significant changes were also not obtained during the evaluation of the PPT in active trigger points, although we can only compare it with our LF-PENS group because in this study only LF was applied.

Opposite to this study, an article published by Rodríguez-Fernández et al (50) with 76 patients, divided into 2 groups, performed an intervention with TENS and placebo, with the application of 10 minutes of burst type TENS, observing a statistically significant increase in PPT in latent trigger points of the upper trapezius muscle, which has been found on chronic conditions like on active MTrPs.

For the secondary outcomes, this study did not observe significant changes in the scores of kinesiophobia after both LF and HF interventions. They reveal a decrease in cervical disability, being statistically significant in both groups, but being inferior to the minimal detectable change of 5 points, limiting the clinical relevance of this effect. These results are in line with the studies carried out by León-Hernández et al (43) and Ziaeifar et al (51) in which after the application of dry needling in active trigger points in the trapezius muscle, they found a decrease in disability that reached the MICD, evaluated with the disability questionnaire of arm, hand, and shoulder.

An article published by Louw et al (52) supported the efficacy of therapeutic education in reducing pain and disability rates, and increasing physical performance for patients with musculoskeletal pain. Another publication suggested that an intervention in education in neurophysiology of pain is necessary to establish guidelines for self-management of the pathology, self-treatment techniques to achieve active coping strategies and strengthen patient involvement in therapy (53).

Future research is needed on the effects of PENS, in which it would be necessary to extend the follow-up, with the aim of observing that parameters (HF or LF) maintain the hypoalgesic effect in the long term, to obtain an improvement in the syndrome of cervical myofascial pain.

Limitations

The present study shows certain limitations. There was heterogeneity of the sample in relation to gender (12 men and 28 women), although, according to the 2011 – 2012 National Health Survey, there is a high prevalence of chronic cervical myofascial syndrome that appears more frequently in women (21.9%) than in men (9.6%), which could be reflected in the study sample (54).

Similarly, limitations of the study could be the wide range of ages between 21 – 75 years (mean = 51.55 years) and the small sample size (40 patients).

Another limitation to observe could be that the treatment for cervical myofascial pain focused exclusively on MTrP of the upper trapezius muscle, and other muscles responsible for neck pain were not evaluated,

although of all the target muscles responsible for neck pain, trapezius is the most frequent. Finally, the absence of a placebo group in the sample, as well as the absence of an intervention in therapeutic education for the maintenance of a long-term effect, could be considered an important limitation.

Conclusions

Low and high frequency PENS combined with deep dry needling showed similar effects, since no differences between groups were observed on any of the outcome measures.

Both low and high frequency PENS generated short-term effects on pain intensity, but not on mechanical hyperalgesia. Both frequencies statistically improved neck disability, but the improvements cannot be considered as clinically relevant. None of the interventions improved fear of movement.

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