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Original article

Effects of dry needling in HIP muscles in patients with HIP osteoarthritis: A randomized controlled trial☆,☆☆

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ABSTRACT

Background: Dry needling (DN) in active myofascial trigger points (MTrPs) is effective to reduce pain, increase range of motion (ROM) and improve physical function in different musculoskeletal disorders. However, there is a lack of studies evaluating the effects of DN in active MTrPs in hip osteoarthritis (OA).
Objective: To determine the short-term effects of DN on pain, hip ROM and physical function in patients with hip OA.
Design: Double-blind randomized controlled trial.
Methods: Thirty patients with unilateral hip OA were randomized into two groups: DN group and sham group. Participants received three treatment sessions. The treatment was applied in active MTrPs of the iliopsoas, rectus femoris, tensor fasciae latae and gluteus minimus muscles. Pain intensity (visual analogic scale), passive hip ROM (universal goniometer and digital inclinometer) and physical function (30s chair-stand test and 20m walk test) were assessed at baseline and after the three treatment sessions.
Results: There was decreased pain intensity, increased hip ROM, and improved physical function following the DN treatment. These improvements were statistically significant ($p < 0.05$) compared to the sham group. The sham group had increased pain intensity and decreased hip ROM ($p < 0.05$).
Conclusion: Pain, hip ROM, and physical function improved after the application of DN in active MTrPs of the hip muscles in patients with hip OA.

1. Introduction

The hip is the second most common joint affected by osteoarthritis (OA) (Woolf and Pfleger, 2003). The prevalence of hip OA ranges from 14.3% to 19.6% (Allen and Golightly, 2015; Iidaka et al., 2016). Hip OA is a common degenerative joint disease that causes musculoskeletal pain, limited range of motion (ROM) and disability (Bennell, 2013). Clinical practice guidelines recommend non-pharmacological conservative treatments to relieve pain and improve physical function in hip OA (Cibulka et al., 2017; Hochberg et al., 2012). These improvements could slow the disease progression (van Dijk et al., 2010).

Pain is the most frequent complaint of patients with hip OA although the intensity of hip pain is not directly related to radiographic findings (Pereira et al., 2016). Patients with hip OA avoid painful movements, which reduces hip function (Heuts et al., 2004; Vlaeyen and Linton, 2000). This process may result in a loss of hip ROM, lower limb physical function and independence during daily activities (Holla et al., 2014). For this reason, treatments based on pain reduction could

☆ This study design, protocol and consent forms were performed in accordance with the Helsinki Declaration of 1964 (revised in Fortaleza, 2013). The ethical approval for this study was obtained from the Clinical Research Ethics Committee of Aragón (PI17/0182) and it was registered in ClinicalTrials.gov, NCT03202056.

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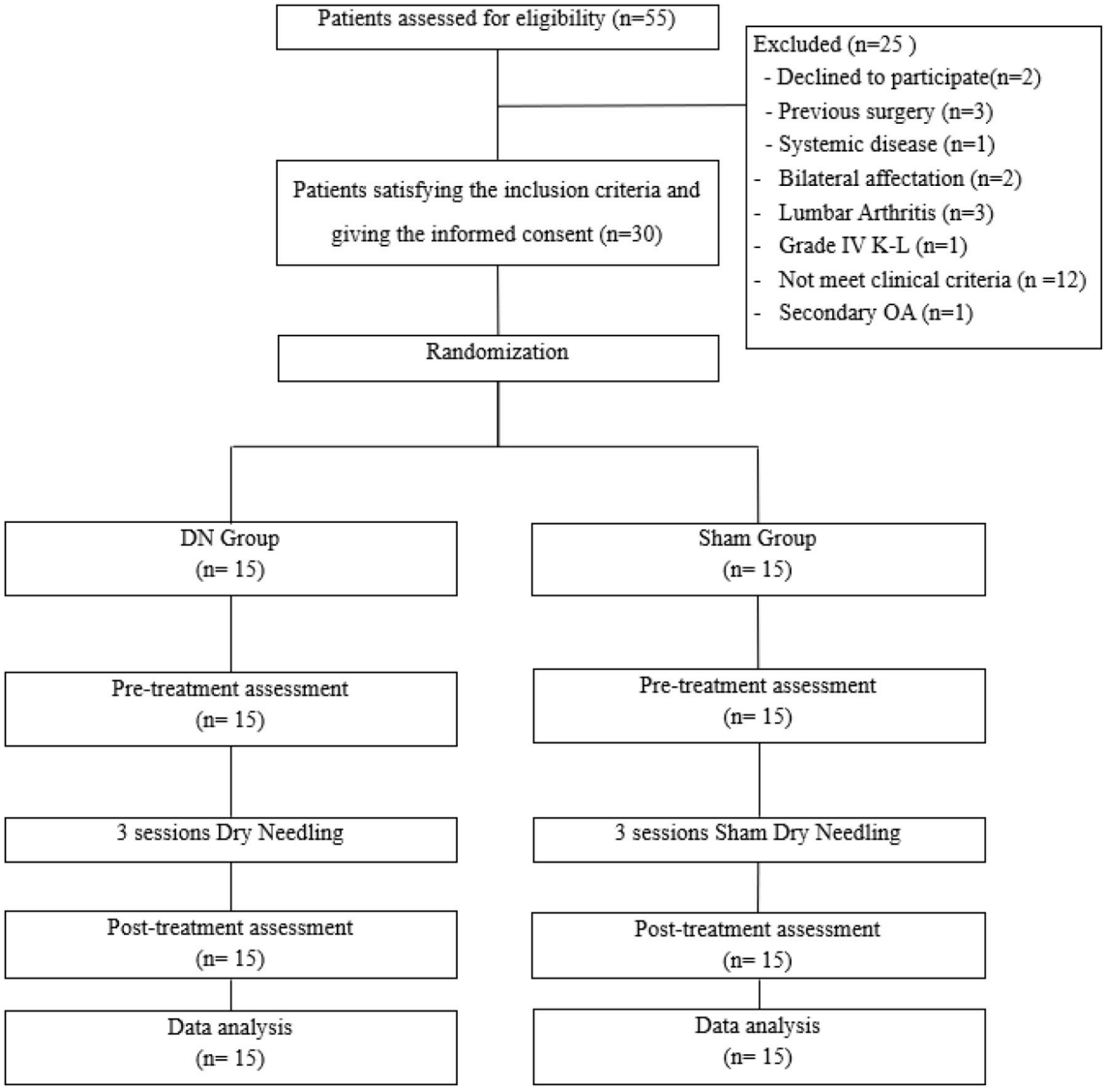

Fig. 1. Flowchart diagram.

Table 1
Participants characteristics at baseline.

Characteristics	DN Group (n = 15)	Sham Group (n = 15)	Significance
Gender (male/female)	8/7	9/6	$X^2 = 0.1$; p = 0.713
Age (years)	55.5 ± 4.7	58.6 ± 6.6	U = 82.5; p = 0.217
Time since diagnosis (months)	64.4 ± 79.6	72.2 ± 91.2	U = 97.5; p = 0.539
BMI (Kg/cm2)	27.5 ± 3.6	26.9 ± 4.4	U = 101.5; p = 0.653
Grade K-L (II/III)	9/6	6/9	$X^2 = 1.2$; p = 0.273

DN: Dry Needling; BMI: Body Mass Index; K-L: Kellgren and Lawrence. Values are expressed as mean ± SD except where otherwise indicated.

increase physical function and improve the prognosis of patients with hip OA (van Dijk et al., 2010).

Currently, several studies have shown the relationship between osteoarthritic pain and active myofascial trigger points (MTrPs) (Alburquerque-García et al., 2015; Dor and Kalichman, 2017; Henry et al., 2012). Active MTrPs are tender points located in a taut band of skeletal muscle that cause spontaneous pain, referred pain, limited joint ROM and muscle weakness (Gerwin, 2014). These clinical characteristics are similar to those found in patients with hip OA. However, to our knowledge, MTrPs have never been considered in hip OA studies.

Dry needling (DN) is a common procedure to treat MTrPs and consists of the use of a needle to eliminate or inactivate the MTrP (Dommerholt et al., 2006). DN is effective in reducing pain intensity, increasing ROM and improving physical function in patients with knee OA (Itoh et al., 2008) and after total knee arthroplasty (Mayoral et al., 2013; Núñez-Cortés et al., 2017). We hypothesized that DN in active MTrPs of the hip muscles would improve the symptoms in patients with hip OA. Knee OA.

Thus, the primary purpose of this study was to determine the short-term effects of DN on hip pain in patients with hip OA. The secondary purpose was to evaluate the short-term effects of DN on hip ROM and physical function in these patients.

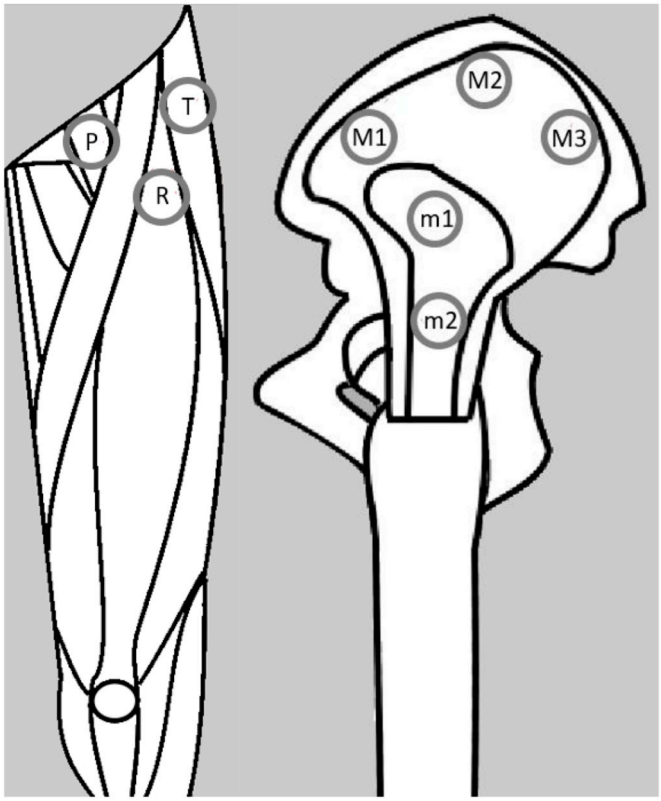

Fig. 2. Pictorial representation of the active MTrPs. P: Iliopsoas muscle; R: Rectus femoris muscle; T: Tensor Fasciae Latae; M1: Anterior part of gluteus medius muscle; M2: Middle part of gluteus medius muscle; M3; Posterior part of gluteus medius muscle; m1: Superior part of gluteus minimus muscle; m2: Inferior part of Gluteus minimus muscle.

Table 2
Active MTrPs at baseline.

Muscle	DN Group	Sham Group	Significance
Iliopsoas	80.0% (12)	80.0% (12)	p = 1.000
Rectus Femoris	86.7% (13)	66.7% (11)	p = 0.390
Tensor Fasciae Latae	86.7% (13)	100% (15)	p = 0.483
Gluteus medius MTrP 1	0.0% (0)	26.7% (4)	p = 0.100
Gluteus medius MTrP 2	20.0% (3)	26.7% (4)	p = 1.000
Gluteus medius MTrP 3	13.3% (2)	13.3% (2)	p = 1.000
Gluteus minimus MTrP 1	6.7% (1)	0.0% (0)	p = 1.000
Gluteus minimus MTrP 2	33.3% (5)	33.3% (5)	$X^2 = 1.0$; p = 1.000

DN: Dry Needling; MTrP: Myofascial Trigger Point. Values are expressed as percentages and frequencies (n) except where otherwise indicated.

2. Material and methods

2.1. Study design

We conducted a double-blind randomized placebo-controlled trial between January and September 2018. This study was registered at www.clinicaltrials.gov with the registration number NCT03202056. The ethical approval for the study was obtained from the Clinical Research Ethics Committee of Aragón (PI17/0182). Patients provided written and informed consent to participate in this study. The study was carried out according to CONSORT guidelines.

2.2. Participants

Thirty patients (mean age 57.0 ± 5.7 years; 56.7% females) were recruited from private practice physiotherapy clinics or referred by general practitioners and orthopedic surgeons.

The inclusion criteria were: unilateral primary hip OA according to the clinical criteria of the American College of Rheumatology (Altman et al., 1991), a grade II or III Kellgren & Lawrence (K-L) classification (Kellgren and Lawrence, 1957) in their most recent hip X-rays, 50–70 years of age and presence of at least one active MTrP in the hip muscles.

The exclusion criteria were: previous lower limb replacement surgery, neurological, vascular or other lower extremity musculoskeletal conditions that affected sensation, gait or functional performance, previous physiotherapy treatment to the hip in the last three months, DN contraindications (local infection, bleeding disorders, immune suppression, or significant fear of needles), previous experience of DN technique to maintain blinding of patients or inability to understand the instructions and complete the study assessments.

All participants were randomly assigned to the DN group or the sham group. An external assistant randomized the participants to the groups using the Research Randomizer (Version 4.0) computer software. Both the examiners and the patients were blinded to the group assignment.

2.3. Interventions

DN and sham interventions were carried out by the first author, blinded to the measurements, who received training in DN and had 4 years of clinical experience.

All patients received three treatment sessions according to the assigned group. One session per week was applied according to the findings described by Domingo et al. (2013). No exercise program or physical therapy modalities were added to the intervention. Patients were asked not to take any nonsteroidal anti-inflammatory or muscle relaxant drugs.

The physical examination findings allowed the clinicians to determine which muscle had to be targeted. Active MTrPs were located by manual palpation in the hip muscles according to Travell and Simons criteria (Simons et al., 2007). Manual palpation is the current gold standard for MTrPs diagnosis (Shah et al., 2015) and has shown moderate to excellent reliability in lower limb muscles (Rozenfeld et al., 2017; Zuil-escobar et al., 2016). The overlying skin was cleaned with an antiseptic solution and the active MTrPs were immobilized between the index and middle finger. Three active MTrPs were treated at most in each session.

In the DN group, the standard single-use sterile acupuncture needle (0.25 mm × 50 mm) was inserted perpendicularly through the skin and moved forward until the MTrP was reached. To minimize the pain of insertion a certain pressure was applied to the skin with the insertion tube. Hong's fast-in and fast-out technique was used with the aim of eliciting local twitch response (Hong and Torigoe, 1995, 1994). After the needle was removed, pressure with a cotton ball was maintained to prevent bleeding.

The sham group received a simulated DN technique that has shown to be valid (Tough et al., 2009). The blunted needle was applied to MTrPs to provoke a pricking sensation without penetrating the skin. This form of sham application enables the patient to be blinded to group allocation (Anna et al., 2008; Park et al., 2002). Sham DN was also added in the same regions with the same dose as the DN group.

2.4. Outcome measures

Outcome measures were evaluated by two blinded examiners.

The primary outcome measure, pain intensity, was recorded at baseline and after the three treatment sessions. A 10-cm Visual Analogic Scale (VAS) was used to measure pain intensity, in which 0 represented "no symptoms" and 10 "the most intense pain imaginable". The Intraclass Correlation Coefficient (ICC) of VAS in patient with OA is 0.97 (Alghadir et al., 2018).

The secondary outcomes, hip ROM in the three planes of motion and

Table 3
Baseline, final values, differences and effect sizes for pain, ROM and physical function.

Outcome Group	Baseline	End of treatment	Within-Group changes	Within-Group Effect sizes	Between-group differences in change scores	Between-Group Effect Sizes
VAS (0–10)						
DN	2.1 ± 1.8	0.4 ± 0.8	0.003	1.2	2.1	0.9
Sham	1.3 ± 1.6	2.6 ± 2.5	0.043	−0.6	(0.7–3.5; 0.004)	
Hip Internal Rotation						
DN	11.8 ± 5.3	19.8 ± 7.8	0.001	−1.2	10.8	2.0
Sham	10.4 ± 4.4	9.0 ± 3.7	0.036	0.3	(15.4–6.2; 0.001)	
Hip External Rotation						
DN	18.1 ± 4.0	26.9 ± 4.7	0.001	−2.0	10.7	2.1
Sham	18.3 ± 6.0	16.2 ± 6.3	0.043	0.3	(14.0–5.6; 0.001)	
Hip Flexion						
DN	92.4 ± 9.5	108.7 ± 8.1	0.001	−1.8	20.4	2.0
Sham	94.2 ± 8.4	88.3 ± 11.2	0.018	0.5	(27.7–13.0; 0.001)	
Hip Abduction						
DN	6.6 ± 3.4	12.2 ± 3.8	0.001	−1.5	6.7	1.8
Sham	7.1 ± 4.6	5.4 ± 3.4	0.029	0.4	(9.5–4.0; 0.001)	
Hip Adduction						
DN	4.8 ± 2.7	8.9 ± 2.9	0.001	−1.4	5.5	2.0
Sham	4.5 ± 2.6	3.4 ± 1.9	0.080	0.4	(7.4–3.6; 0.001)	
Hip Extension						
DN	−20.4 ± 7.8	−10.0 ± 6.7	0.001	−1.4	14.0	2.4
Sham	−19.4 ± 5.8	−24.1 ± 5.4	0.003	0.8	(18.7–9.5; 0.001)	
20m Walk Test						
DN	16.8 ± 3.3	13.5 ± 1.9	0.001	1.2	2.8	1.2
Sham	15.5 ± 1.7	16.3 ± 2.2	0.073	−0.4	(1.2–4.4; 0.001)	
CS Test						
DN	9.8 ± 3.7	15.3 ± 4.1	0.001	−1.4	4.6	1.1
Sham	10.3 ± 3.3	10.7 ± 3.7	0.425	−0.1	(7.5–1.6; 0.003)	

VAS: Visual Analogic Scale; DN: Dry needling; CS: 30 Seconds Chair-Stand test. Values are expressed as mean ± SD for baseline and final means and as mean (95% confidence interval) for within-group and between-group change scores.

physical function were registered at baseline and after the three treatment sessions. Hip ROM was recorded using a universal goniometer, according to the procedure described by Pua et al. (2008). In previous studies, hip ROM measurements showed excellent test-retest reliability for all the movements (ICC ranged from 0.89 to 0.97) (Pua et al., 2008). Physical function was evaluated with the 30s Chair-Stand (CS) test and the 20m walk test. CS test records the number of sit-stand-sit cycles that the patient can complete in 30 s. CS test is a reliable test that assesses the function and strength of the lower limbs (ICC = 0.88) (Bieler et al., 2014). 20m walk test counts the time the patient needs to complete 20 m long. This test is a reliable test that measures the physical function and gait speed (ICC = 0.98) (Motyl et al., 2013).

2.5. Sample size determination

The sample size was calculated using Minitab® 13.0 program, conceptualized as a superiority study. The calculation was based on the primary outcome, estimated for a two-tailed *t*-test accepting a 5% alpha error rate and desiring 80% power, and accounting for up to 15% attrition. The sample size was determined assuming a standard deviation of 1.83 previously reported in a pilot study and a between mean difference of 2 points considered as the minimum clinically important difference (MCID) in the VAS. The estimated sample size was calculated to be 15 patients per group.

2.6. Statistical analyses

SPSS 20.0 software was used for all statistical analyses. Mean and standard deviations were calculated for quantitative variables. Frequencies and percentages were calculated for qualitative variables. The Shapiro-Wilk test was used to assess for the normal distribution of quantitative data. Between groups comparisons of baseline clinical and demographic variables were analyzed by Student's *t*-test or the Mann-Whitney *U* test, for normally distributed data or non-normally distributed data respectively. The Chi-square test (X^2 test) or Fisher exact test were used for the nominal variables according to the conditions of each of them. A two-way analysis of variance (ANOVA) was used to investigate the differences in outcomes with time (baseline and end of the treatment) as the within-subjects factor and group (DN, sham) as the between-subjects factor. A p-value < 0.05 was considered statistically significant. The effect size (Cohen's d) was also calculated, to estimate the magnitude of the differences within and between groups. The magnitude of difference was classified as small if the value of Cohen's d ranged from 0.2 to 0.5, as moderate if it ranged from 0.5 to 0.8 or, as large if Cohen's d value was greater than 0.8. Moderate and large magnitudes of effect size were considered indicators of appropriate statistical power (Cohen, 1988).

3. Results

Fifty-five consecutive patients with hip pain were screened for eligibility criteria. Twenty-five patients were excluded: 23 of them did not fulfill the inclusion criteria, and 2 declined to participate for personal reasons. Thirty patients met the eligibility criteria, agreed to participate and were randomized into the DN group (n = 15) or sham group (n = 15). The study flowchart is shown in Fig. 1. Demographics' data were similar for all variables between groups (Table 1).

The location of the active MTrPs in the hip muscles is shown in the Fig. 2. The mean number of active MTrPs identified was (3.43 ± 0.8) in the intervention group and (3.47 ± 1.0) in the sham group (Table 2). There were no differences in the proportion of muscles in which MTrPs were treated (X^2 = 7.3, p = 0.291). The iliopsoas, rectus femoris, tensor fasciae latae, and gluteus minimus were the main muscles treated.

After the third session, a two-way ANOVA showed significant Group by Time interaction for the intensity of pain (F = 9.58, p = 0.004). A significant Group by Time interaction was detected for hip internal rotation (F = 23.18, p = 0.001), external rotation (F = 22.93, p = 0.001), flexion (F = 32.19, p = 0.001), abduction (F = 25.72, p = 0.001), adduction (F = 36.20, p = 0.001) and extension

($F = 39.25$, $p = 0.001$). An ANOVA also revealed a significant Group by Time interaction for all functional tests (CS: $F = 10.23$, $p < 0.003$; 20m Walk test: $F = 13.08$, $p < 0.001$). Pain intensity decreased, hip ROM in three planes increased, and physical function improved following the DN treatment ($p < 0.05$). The results achieved for all the variables in the DN group showed a large effect size ($d > 0.8$). The sham group pain intensity increased, and hip ROM decreased except for hip adduction. Baseline and post-intervention data, as well as within-group and between-groups differences for outcome variables are shown in Table 3.

4. Discussion

To our knowledge, this is the first study to investigate the short-term effects of DN in patients with hip OA. This randomized clinical trial successfully demonstrated that DN significantly decreased pain intensity, increased hip ROM in three planes and improved lower limb physical function compared to sham DN in patients with hip OA.

The outcomes of this study have shown a decrease in pain intensity with a large effect size (E.S. = 1.2) in the DN group. Pharmacological treatments like acetaminophen (Towheed et al., 2006) and non-steroidal anti-inflammatory drugs (NSAIDs) (Bjordal et al., 2004) have also shown to be effective to reduce pain intensity in patients with hip OA, but no study has compared both treatments. Other non-pharmacological conservative treatments such as manual therapy (Brantingham et al., 2012), patient education (Poulsen et al., 2013) or therapeutic exercise (Bieler et al., 2017) have reported a decrease in pain intensity in patients with hip OA. However, the interventions applied in these studies were longer than 3 treatment sessions. Several studies have reported improvements in pain with bupivacaine and lidocaine injections (Henry et al., 2012; Yentür et al., 2003), DN (Itoh et al., 2008) and DN combined with other techniques in patients with OA (Núñez-Cortés et al., 2017), but this is the first study that has investigated the effects of three sessions of DN in isolation in hip OA.

The mechanism of DN to improve musculoskeletal complaints is unclear. It has been proposed that the taut band of MTrPs may cause local compression and impair arterial inflow which could reduce the supply of oxygen, calcium and other nutrients necessary for muscle function. This process may precipitate the synthesis and release of endogenous algogenic biochemical and inflammatory substances that enhance nociception (Hong, 2008; Shah et al., 2008). The analgesic effects of DN in MTrPs are related to the modulation of several biochemical substances associated with pain, inflammation and hypoxia (Hsieh et al., 2012).

This study has shown that three sessions of DN improved hip ROM significantly. The outcomes achieved in hip flexion, extension, abduction, adduction, internal rotation and external rotation ROM are superior to standard error of mean (SEM) values reported in previous studies (Klässbo et al., 2003; Pua et al., 2008). Changes in hip flexion, extension, external and internal rotation ROM exceeds the MCID values reported by Pua et al. (2008). The increase of hip ROM could be related to the changes in pain intensity. Previous studies have suggested that the analgesic status could influence joint mobility (Brisson et al., 2018). Therefore, patients with less pain intensity could move the hip joint in a higher ROM.

The DN group has also shown an improvement on physical function higher than the MCID values described for the 20m walk test and CS test (Bieler et al., 2014; Motyl et al., 2013). The improvements in physical function following the DN technique could have resulted from the decrease in pain intensity, and the increase in hip ROM. Difficulties in functional tasks such as walking and sitting, may influence activity limitations and physical deconditioning. An improvement in physical function could avoid physical decline (Holla et al., 2014, 2012). It is important to highlight that in this study there was no associated training programme unlike other studies (Edwards and Knowles, 2003; Núñez-Cortés et al., 2017).

Although there are no studies about the prevalence of active MTrPs in patients with hip OA, our sample presented more active MTrPs in hip flexors muscles. Hip flexion movement is involved in tasks such as walking, sitting or climbing. The overuse of these muscles could be related to higher MTrPs prevalence. The muscles most treated in both groups were the iliopsoas, rectus femoris, tensor fasciae latae and gluteus minimus. During the physical examination, the pain evoked with the manual stimulation of the MTrPs of these muscles was recognized by the patients as their pain. The dysfunction of these muscles has been associated with uncontrolled movements of the hip joint, causing aberrant arthrokinematics and increasing the disability (Lewis et al., 2007). Also, these muscles are directly related to hip capsule and ligaments (Birnbaum et al., 2004; Cooper et al., 2015; Flack et al., 2014; Ryan et al., 2014). DN has shown positive effects in muscle relaxation and elasticity of the capsule and surrounding muscles (Ma et al., 2010; Shah and Gilliams, 2008) which could improve also the hip arthrokinematics. These positive effects could explain the changes showed in the DN group.

The sham group has significantly increased pain intensity and decreased hip ROM. The changes in pain intensity were clinically relevant and statistically significant. The changes in hip ROM were statistically significant, but these results were lower than the SEM described by Pua et al. (2008). To our knowledge, this is the first study to evaluate the effects of three sessions of sham DN in hip OA. Previous studies have not shown changes after the sham DN application (Itoh et al., 2008). However, Dieppe et al. (2016) suggested that sham treatments in OA may result in changes in the central nervous system. These changes provoke a pain perception alteration which could explain the outcomes achieved in the sham group.

The positive effects showed in the DN group highlight the relevance of treating the active MTrPs of the hip muscles in patients with mild to moderate symptomatic hip OA. All the muscles on the hip region are important in a degenerative condition but according to our results, it would be necessary to assess and treat active MTrPs in iliopsoas, rectus femoris, tensor fasciae latae and gluteus minimus muscles.

There are potential limitations. First, we included grade II-III K-L, therefore the results cannot be extrapolated to grade IV K-L. Second, the effects were only assessed after the end of the sessions, medium and long-term follow-ups were not measured. Third, the researcher that performed the subjective manual palpation for MTrPs diagnosis was an experienced clinician, the training for MTrPs assessment could be necessary to avoid the risk of bias. Finally, only DN therapy was applied, however, a multimodal physical therapy intervention is recommended to treat patients with hip OA. Future studies should include imaging tools for MTrPs diagnosis such as ultrasonography and ultrasound elastography (Sikdar et al., 2009; Turo et al., 2015), medium and long terms of follow-ups, a longer treatment period and multimodal therapeutic approaches.

5. Conclusion

This study showed that pain decreased, hip ROM increased, and physical function improved after three treatment sessions of DN in active MTrPs of the hip muscles in patients with hip OA.

Clinical trials ID

NCT03202056.

Declaration of interest

None.

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