Clinical research

Orthopedics and Traumatology

Effects of dry needling of the gluteus medius muscle in individuals with chronic ankle instability: a randomized, single-blinded controlled clinical trial

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Abstract

Introduction: Lateral ankle sprain (LAS) is one of the most common musculoskeletal injuries in sports and the general population. The goal of the present study was to evaluate the effectiveness of dry needling (DN) of the gluteus medius muscle in patients with chronic ankle instability (CAI).
Material and methods: A two-arm (1 : 1), single-blinded (participants), randomized clinical trial was performed in 40 subjects with CAI who were divided into two groups: an intervention group that received one session of DN in the most hyperalgesic gluteus medius myofascial trigger point (MTrP), (n = 20) and a control group (n = 20). Dynamic balance, pain intensity, pain pressure threshold (PPT) in the anterior talofibular ligament (ATL) and ankle dorsiflexion range of motion (ROM) were assessed at baseline, post-intervention, and a 1-week follow up.
Results: The intervention group showed significantly greater improvements than the control group in anterior and medial dynamic balance (p = 0.001), PPT at the ATL (p = 0.002) and ankle dorsiflexion ROM (p = 0.001).
Conclusions: The findings of the present study suggest that DN at the most hyperalgesic MTrP of the gluteus medius may increase the anterior and medial dynamic balance, ankle ROM and PPT at the ATL in individuals with CAI in the short term. Pain intensity improved in both groups. Future studies should investigate DN as a potential adjunct to a physical therapy program for individuals with CAI.

Key words: pain, dynamic balance, dry needling, ankle instability.

Introduction

Lateral ankle sprain (LAS) is one the most common musculoskeletal injuries in sports and the general population [1]. In addition, the societal cost is as high as $6.2 billion annually [2]. Patients who suffer an LAS episode commonly report a decrease in quality of life, foot and ankle osteoarthritis, a lack of lower limb functionality, and, thus, a decrease in sports performance [2]. Approximately 70% of these individuals may

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develop chronic ankle instability (CAI), a disorder characterized by subjective instability, recurrent episodes of "giving way" and sprains, loss of function, and disturbances in postural control, reflex function, mechanical function, and sensorimotor disturbances [3]. Moreover, Nabb *et al*. [4] reported that proprioception, balance, and motor control may be altered in patients with CAI. Several authors have described altered gait kinematics, ligament laxity, range of motion (ROM), and synovial changes in patients with CAI [5–7]. The combination of these symptoms may increase the risk of recurrent LAS, which has been associated with a laterally deviated center of pressure and impaired balance during walking [8, 9].

It has been reported that patients with CAI show an increase of peroneus longus (PL) activity prior to the initial ground contact [10]. In addition, during a unilateral drop jump, patients with CAI showed a decrease of PL muscle activation compared with healthy individuals assessed by electromyography [11]. Hale *et al*. [12] argued that the existence of disturbances in both peripheral and centrally mechanisms may develop after injury, which produces alterations in postural control even after rehabilitation programs. Moreover, the authors suggested that lower-extremity balance training could have benefits for foot and ankle function and balance. Although most of the research on muscular motor control and patterns has been carried out in proximal ankle joints in subjects with CAI (e.g. decreasing muscle activation in muscles surrounding the ankle, knee and hip) [13], Webster and Gribble [14] observed a decrease of gluteus maximus (Gmax) muscle activity in patients with CAI during a single leg rotational squat task.

Postural control plays an important role in the development of adequate muscular activation and a coordinated gait pattern. The Star Excursion Balance Test (SEBT) was reported to be a reliable and valid tool to assess the dynamic postural control in individuals with and without ankle pathology [15]. In addition, patients with CAI have been shown to have deficits in postural control compared with healthy individuals, as measured by the SEBT. Likewise, the Y-balance test (YBT) is a variation of the SEBT used to assess lower-limb dynamic balance, with excellent reliability (intra-rater ICC = 0.85–0.91; inter-rater ICC = 0.91–0.99) [16], and has been used in previous studies [17].

Ayotte *et al*. [18] reported that appropriate Gmax and gluteus medius (Gmed) function is necessary for maintaining postural stability during weight-bearing activities. In this line, Jaber *et al.* compared the postural control and electromyographic (EMG) activity between individuals with and without CAI. The results showed that alterations in proximal and distal muscle activity may adversely affect movement and postural control, which may lead to long-term functional impairment [19]. Thus, the authors suggested that interventions and training programs focused on the hip and ankle muscles could benefit the prevention and management of CAI.

Myofascial trigger points (MTrPs) located at the Gmax and Gmed have been associated with muscle weakness, biomechanical disturbances of the lower limbs or lumbar pathology [20]. MTrPs were defined as "a hyperirritable nodule in a taut band of skeletal muscle that is palpable and tender during physical examination" [21]. In addition, MTrPs have been associated with overuse, motor control disturbances, injuries and pain. Two types of MTrPs have been described: active MTrPs that reproduce symptoms and referred pain, and latent MTrPs, which are asymptomatic but palpable on clinical examination. Regarding the diagnosis, active MTrPs may elicit recognizable pain and a local twitch response upon needle penetration [20].

Dunning *et al*. [22] argued that dry needling (DN) have benefits in the management of neuromusculoskeletal pain syndromes, such as the treatment of MTrPs. In addition, Salom-Moreno *et al*. [23] reported that DN is an effective approach for the treatment of sensory and motor factors in MTrPs. Several authors have reported the benefits of the DN in pain management. For example, Hu *et al*. [24] conducted a meta-analysis in patients with low back pain, showing that DN was more effective than acupuncture for reducing pain intensity. In the same line, a systematic review and a meta-analysis carried out by Gattie *et al*. [25] reported that DN was superior to sham treatment for short- and mid-term follow-ups for musculoskeletal pain conditions. In addition, DN of the sternocleidomastoid muscle has been reported to improve cervical muscle motor control at 1-month follow-up in individuals with neck pain [26]. Sánchez-Mila *et al.* [27] reported that DN combined with a Bobath program improved ROM and balance and also reduced spasticity in patients who had suffered a stroke.

Several authors have suggested that improved motor control and function of hip muscles, such as the Gmax and Gmed, may benefit lower-limb stability. However, evidence for the use of DN to manage CAI remains limited. Therefore, the aim of the present study was to determine the effect of DN applied to the most hyperalgesic latent MTrP in the Gmed on ankle ROM, dynamic balance and the pressure pain threshold (PPT) at the anterior talofibular ligament (ATL) and MTrPs of the Gmed muscle compared with a sham intervention in individuals with CAI. We hypothesized that individuals receiving DN would exhibit greater improve-

ments in ankle ROM, balance and PPT than those receiving a sham intervention.

Material and methods

Design

A two-arm (1 : 1), participant-blinded, randomized clinical trial was performed from September 2019 to January 2020 and reported in accordance with the CONsolidated Standards of Reporting Trials (CONSORT) guidelines [28].

Sample size calculation

G*Power software was used to calculate the sample size based on the between-group difference in anterior talofibular ligament pressure pain threshold (ATL-PPT; kg/cm²) observed in a pilot study (n = 12), which included 6 subjects in group A (intervention; 4.42 ±0.25) and 6 subjects in group B (control; 4.22 ±0.21). The calculation used a power of 0.80, an αerror of 0.05, an effect size of 0.86, and a one-tailed hypothesis. The calculated sample size was 36 participants. However, 40 participants were recruited for this study.

Participants

A total of 40 participants with CAI, defined according to the position statement of the International Ankle Consortium [29], were recruited from a care center and allocated to two groups: intervention (n = 20) and control (n = 20) (Figure 1).

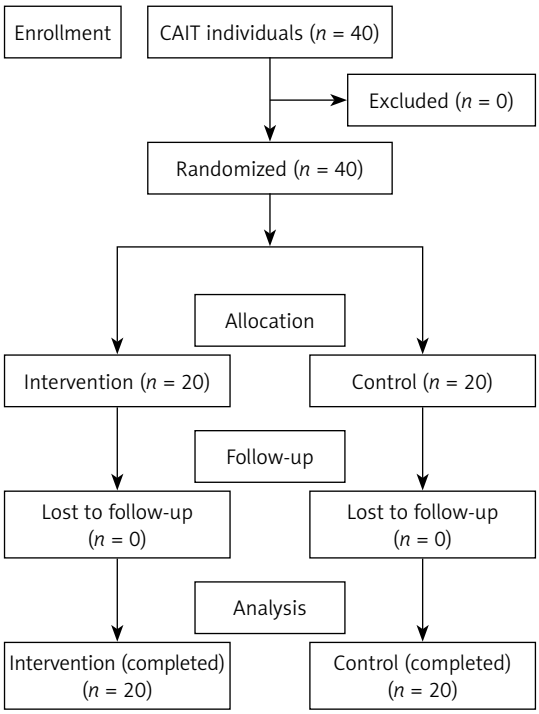

Figure 1. Flow chart diagram

The inclusion criteria were as follows: a history of at least two recurrent ankle sprains with inflammatory symptoms (e.g., pain or swelling) and at least two episodes of "giving way" in the 6 months before study enrollment [5]. Participants were excluded if they had no history of ankle sprain, a history of vestibular disorders, lower-limb surgery within the previous 12 months (e.g., for fractures or muscular tears), or had received physiotherapy, medical, or pharmacological treatment within the previous 3 months [19].

Randomization and blinding

Before the intervention, randomization was performed using the free software available at Randomization.com, with a 1 : 1 allocation ratio, assigning participants to group A (intervention) or group B (control). Participants were unaware of their group allocation.

Interventions

Participants received one intervention and underwent three assessments: pre-intervention, post-intervention, and at the 1-week follow-up. We used the same needles (0.32 × 40 mm) for both interventions. In addition, the interventions were performed by the same therapist, with more than 10 years of experience in DN technique for the management of MTrPs. Before needle insertion, the area was disinfected with skin antiseptic. Immediately after the intervention, the therapist applied pressure to the skin with a cotton bud to limit bleeding.

Intervention group

The intervention group received a single session of DN to the ipsilateral Gmed muscle of the affected limb, using Hong's "fast in, fast out" technique, which involves multiple rapid needle insertion, following previous guidelines [30, 31]. Each participant received the same DN treatment in the most hyperalgesic latent MTrP located on the Gmed muscle.

Control group

Following the guidelines of Pecos *et al.* [32], the control group received the same protocol on the ipsilateral Gmed muscle of the CAI lower limb, but the needle was inserted 1.5 cm medially from the MTrP (outside the MTrP location).

Outcome measurements

PPT was defined as the amount of pressure applied to a target point until the sensation of pain first occurs [33]. For the present study, PPT was assessed from 0 to 10 kg/cm² with a mechanical

algometer (FDK/FDN, Wagner Instruments, Greenwich, CT). This algometer has been reported to be reliable, sensitive, and reproducible for latent MTrP assessments [34–36]. The most hyperalgesic latent MTrP in the Gmed and the ATL were assessed. Three measurements were taken at each site, with a 30–60 s rest interval between measurements.

The YBT consists of three lines marked on the floor in the anterior posteromedial and posterolateral directions. Following the Plisky *et al.* [16] procedure, the posterior lines were located 135° from the anterior line with 45° between the posterior lines. Before the test, individuals viewed an instructional video to familiarize themselves with the procedure. After the demonstration, participants practiced six trials on each leg of the three directions prior the formal assessment [16]. Participants stood barefoot at the center of the "Y" mark. Each participant was required to maintain a single-leg stance on the test limb while reaching the maximum distance in anterior, posterolateral, and posteromedial directions. Participants placed their hands on their hips, and the stance heel had to remain in contact with the ground. If any criterion was violated during a trial, the trial was repeated. To calculate normalized YBT values, each participant's leg length was measured in the supine position, from the anterior superior iliac spine to the medial malleolus [37]. Reach distances were measured in centimeters. Values were normalized by dividing the mean reach distance by the participant's leg length and multiplying by 100%.

Maximal ankle dorsiflexion ROM was evaluated using a standardized weight-bearing lunge test. Participants moved the knee towards the wall while keeping the heel in contact with the ground; the maximum dorsiflexion position was recorded. The goniometer was aligned with the fibula using the mobile arm and with the fifth metatarsal head using the stationary arm [38]. For each measurement, the evaluator passively moved the ankle from a neutral baseline position into dorsiflexion until a firm end-feel was reached.

All the outcome measurements were performed by the same investigator (G.J.C).

Statistical analysis

SPSS 23.0 software (IBM SPSS Statistics, Armonk, NY; IBM-Corp) was employed for the statistical analysis. The Kolmogorov-Smirnov test was used to assess the normality of the data distribution. Student's *t* test was used to compare age, weight, height, body mass index (BMI), and Cumberland Ankle Instability Tool (CAIT) scores between groups. Student's *t*-test was also used to compare baseline values of the main outcome variables between groups. To assess the effects of time (within-subject factor) and treatment group (between-subject factor) on the dependent variables, a two-way repeated-measures analysis of variance (ANOVA) was performed. The Greenhouse–Geisser correction was applied when Mauchly's test indicated a violation of sphericity. Tukey's post hoc test was used for multiple comparisons. Effect sizes were calculated using the eta-squared (η^2) coefficient. For non-parametric data, the Friedman test and Wilcoxon signed-rank tests were used for within-group comparisons, while the Mann–Whitney *U* test was used for between-group comparisons. Statistical significance was set at $p < 0.05$, with a type I error rate (α) of 0.05 and a nominal power of 80% ($\beta = 0.20$).

Results

Regarding Table I, sociodemographic data did not show significant differences between the groups ($p > 0.05$). Moreover, Student's *t* test for the main variables revealed significant differences between groups for ATL-PPT ($p = 0.015$) and VAS ($p = 0.002$) baseline variables. The rest of the variables did not show significant differences ($p > 0.05$) between the intervention and control group. Significant time × group interaction effects were observed for SEB anterior, SEB lateral, SEB medial, dorsiflexion ROM, ATL-PPT, and Gmed PPT. Significant differences were observed between groups for an increase of YBT anterior ($p = 0.001$), YBT medial ($p = 0.001$), dorsiflexion ROM ($p = 0.001$), and ATL-PPT ($p = 0.002$) in favor of the intervention group. In addition, no significant differences were found for Gmed PPT ($p = 0.332$) (Table II).

Table I. Sociodemographic characteristics and CAIT scores of the sample

Data	Total sample ($n = 40$)	Intervention ($n = 20$)	Control ($n = 20$)	*P*-value (intervention vs control)
Age [years]	32.50 ±6.78	33.80 ±6.77	31.20 ±6.70	0.230
Weight [kg]	68.52 ±12.02	70.60 ±13.27	66.85 ±10.65	0.331
Height [m]	1.69 ±0.18	1.66 ±0.25	1.73 ±0.07	0.220
BMI [kg/m^2]	22.81 ±1.35	24.61 ±1.05	25.36 ±1.47	0.350
CAIT	22.30 ±2.24	22.60 ±2.03	22.00 ±2.44	0.405

BMI – body mass index, CAIT – Cumberland Ankle Instability Tool.

Table II. Within-subject time effects and time × group interaction effects for YBT, ankle dorsiflexion ROM, and PPT

Measure	Intervention (n = 20)	Control (n = 20)	Intrasubject effects	
			Time effect F; p (η^2)	Time × group interaction F; p (η^2)
YBT anterior			F = 22.272; p = 0.001 (0.370)	F = 7.425; p = 0.001 (0.163)
Baseline	94.06 ±24.78	97.56 ±8.96		
Post-test	99.28 ±24.56	98.52 ±8.73		
1-week	100.68 ±23.58	99.53 ±8.95		
YBT medial			F = 28.391; p = 0.001 (0.428)	F = 15.075; p = 0.001 (0.284)
Baseline	131.06 ±16.41	134.50 ±15.92		
Post-test	138.80 ±16.46	135.67 ±15.30		
1-week	140.96 ±15.43	136.07 ±14.98		
YBT lateral			F = 9.650; p = 0.001 (0.203)	F = 3.245; p = 0.063 (0.079)
Baseline	120.83 ±21.24	126.12 ±17.21		
Post-test	126.08 ±21.77	127.20 ±16.96		
1-week	126.97 ±19.26	127.96 ±17.11		
1-week	77.0 ±4.8	73.2 ±6.2		
Dorsiflexion ROM			F = 8.436; p = 0.001 (0.182)	F = 7.728 p = 0.001 (0.169)
Baseline	149.15 ±11.89	133.40 ±13.77		
Post-test	152.85 ±12.23	133.55 ±13.53		
1-week	152.25 ±11.03	133.35 ±13.56		
ATL PPT			F = 40.613; p = 0.001 (0.517)	F = 9.372; p = 0.002 (0.198)
Baseline	3.21 ±0.82	3.91 ±0.89		
Post-test	3.92 ±0.93	4.11 ±0.98		
1-week	4.04 ±0.96	4.23 ±1.01		
Gmed PPT			F = 6.559; p = 0.009 (0.147)	F = 1.037; p = 0.332 (0.027)
Baseline	5.46 ±2.16	5.65 ±1.24		
Post-test	5.79 ±2.33	5.77 ±1.23		
1-week	5.91 ±2.29	5.86 ±1.18		

Values are presented as mean ± SD unless otherwise indicated. ATL – anterior talofibular ligament, Gmed – gluteus medius, PPT – pain pressure threshold, ROM – range of motion, YBT – Y-balance test.

Tukey post-hoc analyses showed significant differences between baseline and post-intervention measurements in the intervention group for ATL-PPT, dorsiflexion ROM, and anterior, lateral, and medial YBT scores. Significant differences between baseline and the 1-week follow-up were also observed for these outcomes in the intervention group (Figure 2). Regarding pain intensity, the Friedman test indicated significant differences (p = 0.001) for the intervention group and the control group (p = 0.043). The Mann-Whitney U test indicated a between-group difference (p = 0.004), but post hoc between-group comparisons at the post-intervention and 1-week follow-up assessments were not statistically significant (p > 0.05).

Discussion

To the authors' knowledge, this research study may be the first clinical trial showing improvements in balance, ankle dorsiflexion ROM, and ATL-PPT in individuals with CAI who received a DN intervention in the most hyperalgesic MTrP at the Gmed muscle. In addition, pain intensity benefits were found in both groups. These findings are consistent with those of previous studies reporting improvements in PPT following DN for temporomandibular disorders [39], chronic shoulder pain [40], neck pain [41], patients after knee arthroplasty [42], and plantar heel pain [43]. Moreover, the results of the present study showed significantly greater increases in ATL-PPT in the intervention group than in the control group immediately after the intervention and at the 1-week follow-up. Regarding pain intensity, improvements were observed in both the intervention and control groups immediately after the intervention and at the 1-week follow-up.

A systematic review and meta-analysis conducted by Liu *et al*. [44] suggested that DN at MTrPs may help relieve pain intensity at short- and medium-term in individuals with low back pain in the short to medium term, but its longer-term ef-

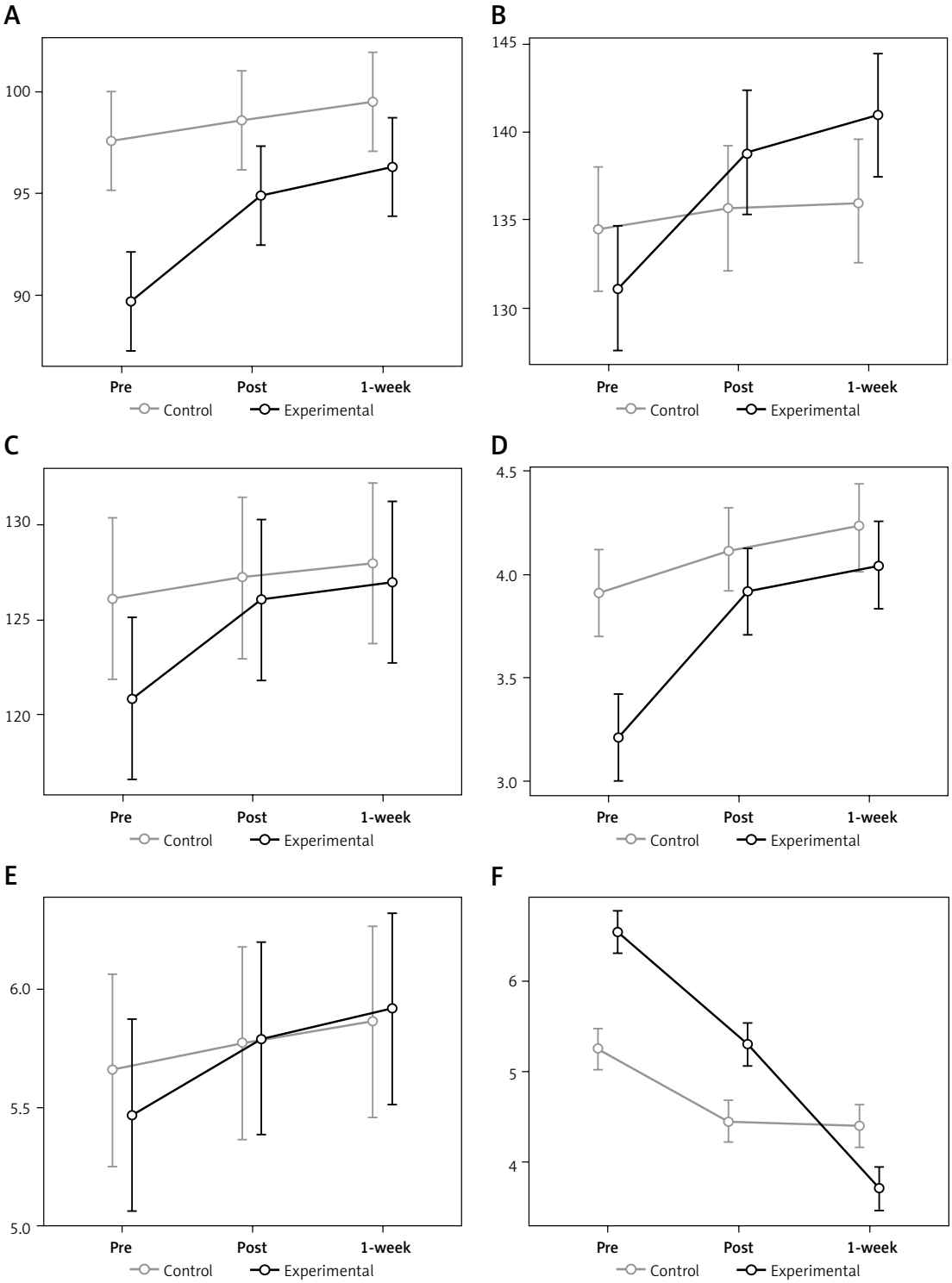

Figure 2. Comparison between intervention and control group measurements for YBT (**A** – anterior, **B** – medial, **C** – lateral), PPT (**D** – ALT-PPT, **E** – Gmed PPT), and VAS (**F**) variables

**Significant differences between groups (treatment × time).*

fects remain unclear. In addition, in a systematic review conducted by the same authors 3 years before, the authors reported that DN was effective in relieving pain intensity in subjects with low back pain at post-intervention and reported that further research is needed to improve the knowledge of the effectiveness with longer follow-ups in DN interventions. Regarding PPT, prior studies reported increases in PPT in the masseter muscle in patients with temporomandibular disorders [39], at the cervical spine (C7) in individuals with chronic neck pain following DN of the upper trape-

zius muscle [45], and in individuals with unilateral shoulder impingement syndrome following DN of the upper trapezius muscle [46]. Our results are consistent with previous findings of short-term improvements in pain-related outcomes, including PPT, following DN. A possible explanation for the observed changes in pain-related outcomes is that rapid needle insertion into an MTrP may stimulate afferent sensory fibers and modulate nociceptive processing at the spinal level, potentially inhibiting pain transmission in the dorsal horn [47].

Several authors have reported the effectiveness of the DN technique (isolated or combined with other therapies) in the ROM. For example, Onat *et al*. [48] found an increase of ROM after the application of DN into the posterior paracervical muscle in individuals with mechanical neck pain. Mendigutia-Gómez *et al*. [49] included a DN treatment for the spastic shoulder muscles in individuals who had experienced a stroke and reported an increase of the ROM. The present study showed the effectiveness of a DN approach increasing the ankle dorsiflexion ROM. These findings could be related to improvements in the dynamic balance of the lower limb, which may contribute to increased ankle mobility. In addition, the findings reported by several authors on ROM after DN differed from those of the present study [50, 51]. Therefore, further research is needed in order to better understand the possible relationship between motor control and ROM.

Regarding dynamic balance, MacKinnon and Winter argued that the gait in the frontal plane is regulated by the subtalar and hip joints [52]. Thus, impaired motor control of the muscles involved in hip kinematics may affect gait in individuals with and without pathology. In addition, Son *et al*. [5] suggested that the ankle joint corrects small disturbances related to a deficient foot position, and the hip correct large disturbances associated with a deficient foot position. Thus, the ankle and hip joints have to work in synergy. When the foot adopts vulnerable positions or in overcompensation ankle kinematics (e.g. during an ankle sprain involving forced inversion), dynamic balance of the lower limb might be maintained through increased activity of the ankle evertors and hip abductors, such as the Gmed. Our results suggested that DN at the most hyperalgesic MTrP in the Gmed muscle may improve dynamic balance in individuals with CAI, with greater improvements than in controls in the anterior and medial YBT directions. In addition, anterior, medial, and lateral YBT scores showed differences between baseline and 1-week follow-up in the intervention group. A possible is that DN may have improved motor control of the Gmed or reduced musculoskeletal pain. Although electromyographic activity was not assessed in the present study, several authors have associated DN of MTrPs with improved muscle function [53, 54]. Son *et al*. [5] reported reduced activation of several lower-extremity muscles in individuals with CAI, including the tibialis anterior (7%), peroneus longus (4%), and vastus lateralis (4%), as well as the Gmed (4%) and Gmax (10%). These findings were interpreted as potentially reflecting alterations in neural activation pathways.

The results of the present study do not provide a gold-standard approach for managing CAI. Thus, these findings provide preliminary evidence that DN may be considered as an adjunct to manual therapy or exercise programs in individuals with CAI. Nevertheless, future studies should investigate the additional benefits of DN when combined with these physical therapy interventions.

Some limitations should be acknowledged in the present study. First, significant baseline differences between groups were found in ATL-PPT and VAS, which may have affected the results for these variables. Second, only one measurement was taken for each YBT variable. Third, electromyographic assessment was not performed to evaluate the muscle activity of the extrinsic foot and the Gmed muscle. Finally, the effects of DN were not assessed beyond the 1-week follow-up. Further research is recommended in order to evaluate muscle activity and MTrP temperature and to assess outcomes over longer follow-up periods in patients with CAI.

In conclusion, the findings of the present study suggested that the DN application in the most hyperalgesic MTrP of the Gmed muscle may improve anterior and medial dynamic balance, ankle dorsiflexion ROM, and PPT at the ATL in the short term in individuals with CAI. Pain intensity improved in both groups. Future studies should consider DN as a possible intervention in conjunction with a physical therapy program for individuals with CAI. Further research is still needed to better understand the mechanisms underlying pain perception following invasive physiotherapy interventions in individuals with musculoskeletal disorders with invasive physiotherapy approaches.

Funding

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Ethical approval

The Clinical Research Ethics Committee of Hospital de la Princesa (Madrid, Spain) approved the study, which was registered at ClinicalTrials.gov (NCT04108390). All participants provided written informed consent before the start of the study. The study was conducted in accordance with the Declaration of Helsinki and relevant ethical stan-

dards for human experimentation. Clinical Research Ethics Committee of Hospital de la Princesa (Madrid, Spain) 25-3-19.

Conflict of interest

The authors declare no conflict of interest.

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