

Effectiveness of dry needling for chronic nonspecific neck pain: a randomized, single-blinded, clinical trial

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Abstract

Chronic neck pain attributed to a myofascial pain syndrome is characterized by the presence of muscle contractures referred to as myofascial trigger points. In this randomized, parallel-group, blinded, controlled clinical trial, we examined the effectiveness of deep dry needling (DDN) of myofascial trigger points in people with chronic nonspecific neck pain. The study was conducted at a public Primary Health Care Centre in Madrid, Spain, from January 2010 to December 2014. A total of 130 participants with nonspecific neck pain presenting with active myofascial trigger points in their cervical muscles were included. These participants were randomly allocated to receive: DDN plus stretching (n = 65) or stretching only (control group [n = 65]). Four sessions of treatment were applied over 2 weeks with a 6-month follow-up after treatment. Pain intensity, mechanical hyperalgesia, neck active range of motion, neck muscle strength, and perceived neck disability were measured at baseline, after 2 sessions of intervention, after the intervention period, and 15, 30, 90, and 180 days after the intervention. Significant and clinically relevant differences were found in favour of dry needling in all the outcomes (all P < 0.001) at both short and long follow-ups. Deep dry needling and passive stretching is more effective than passive stretching alone in people with nonspecific neck pain. The results support the use of DDN in the management of myofascial pain syndrome in people with chronic nonspecific neck pain.

Keywords: Myofascial pain syndromes, Physical therapy, Neck pain, Dry needling, Myofascial trigger point, Stretching

1. Introduction

The prevalence rate of neck pain in the general population ranges from 5.9% to 38.7%, ⁶ with a lifetime prevalence of 14.2% to 71%. ^{67,76} This makes neck pain a public health problem, and a frequent cause of job absenteeism, ²⁶ producing considerable socioeconomic costs. ^{22,46,50} Neck pain may be considered muscular, traumatic, or neurological in origin. ^{11,78,94} Nevertheless, nonspecific neck pain, also named mechanical neck pain, is

diagnosed as cervical pain (with or without radiation) without a known pathological basis as the underlying cause of the complaint. 11,79,95

In recent years, different studies have associated nonspecific neck pain with myofascial pain syndrome (MPS). ^{19,20,63,70,73} A recent study has established a 100% prevalence of MPS in patients with chronic nonspecific neck pain. ²⁰ The most frequently affected muscles were upper trapezius, levator scapulae, multifidi, and splenius cervicis muscles. ²⁰ In addition, recent systematic reviews on the prevalence of myofascial trigger points (MTrPs) in patients with spinal disorders support that they are a prevalent clinical entity, especially in patients with neck pain. ³⁶ The MPS is defined as a cluster of signs and symptoms caused by or associated with MTrPs. An MTrP can be defined as a hyperirritable nodule of spot tenderness in a palpable taut band of a skeletal muscle. The MTrP shows specific characteristics such as being painful on compression and evoking a characteristic referred pain pattern, motor dysfunction, and autonomic phenomena. ⁸⁶

Deep dry needling (DDN) is an invasive technique used for the treatment of MTrPs. ^{27,36,49,69} Although DDN seems to be useful for MPS and MTrP pain management, several systematic reviews ^{24,35,59,89} have established that more high-quality research is needed to support the recommendation for its use. Some recent clinical trials have reported that DDN of MTrPs improves pain, ^{19,63,70,73} joint range of motion (ROM), ^{19,73} and pressure pain threshold (PPT) ^{19,73} over MTrPs in the treated muscles and attains the same effects over pain and PPT in MTrPs located in the referred pain area. ⁵¹ Although these studies show positive and promising results, the lack of proper controls, ^{51,90} small sample size, ^{19,63,70,73} lack of long-term follow-up, ¹⁹ and

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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methodological issues regarding blinding^{51,90} make it difficult to unequivocally establish the effectiveness of DDN in the treatment of MPS and MTrPs.

The aim of this study was first to evaluate the effectiveness of DDN on pain in people with chronic nonspecific neck pain attributed to MPS with active MTrPs in their cervical muscles, and second to evaluate the effectiveness of DDN on mechanical hyperalgesia, neck active ROM, neck muscle strength, and perceived neck disability.

2. Methods

2.1. Design

A randomized, single-blinded, clinical trial was performed between January 2011 and September 2014, at a Primary Health Care Centre at Alcalá de Henares (Madrid, Spain) by the "Physiotherapy in Women's Health Research Group." The study was approved by the Human Research Ethics Committee in Alcalá de Henares at "Principe de Asturias Hospital," Madrid, Spain (protocol number 26/2010). The study was registered at the Clinical Trials.gov register (Trial Registration ISRCTN22726482).

2.2. Participants

Eligible participants from 3 Primary Health Care Centers at Alcalá de Henares Health Area (Madrid) gave written informed consent before participation in the study after chronic nonspecific neck pain had been diagnosed by their primary care doctor. Chronic nonspecific neck pain was diagnosed as cervical pain (with or without radiation) for at least 6 months without a known pathological basis (neurological, trauma induced, etc) as the underlying cause of the complaints. 11,78,88,94 Then, each participant underwent a standardized clinical physiotherapy examination of the neck and upper extremities to determine whether they had MPS.86 Once participants had described their pain pattern, the examiner started the physical examination by locating MTrPs⁸⁶ in the trapezius, levator scapulae, multifidi, and splenius cervicis, as these are demonstrated to be the most prevalent MTrPs among subjects with chronic nonspecific neck pain. 20 Subjects who presented with at least 1 active MTrP in one of these muscles according to the diagnostic criteria established by Simons et al.86 (Table 1) were included in the study. This physical evaluation has good overall interrater reliability. 15,40,79 It was performed by a group-affiliation-blinded physical therapists, with 10 years of experience in the diagnosis of MPS.

The established exclusion criteria were: major trauma documented from the medical history, pregnancy, widespread pain, ⁹⁶ inflammatory, hormonal, and neurological disorders, tendinopathy in the upper extremities, severe psychiatric illness, or if the subject was unable to speak or write Spanish to complete the questionnaires. In addition, participants were excluded if they were under anti-inflammatory, analgesic, anticoagulant, muscle

Table :

Diagnostic criteria of myofascial trigger points.

Recommended essential criteria for identifying myofascial trigger points

Taut band palpable (if muscle accessible)

Exquisite spot tenderness of a nodule in a taut band

Patient's recognition of current pain complaint by pressure on the tender nodule (for active myofascial trigger points)

Painful limit to full-stretch range of motion

relaxant, or antidepressant medication use 1 week before the study commenced, had fibromyalgia syndrome, or had any contraindication to conservative or invasive physiotherapy (infection, fever, hypothyroidism, wounds in the area of the puncture, metal allergy, cancer or systemic disease, or fear of needles). 7,85,87

2.3. Randomization and blinding

Equal numbers of participants were randomly allocated by the computer program EPIDAT version 3.1 (Xunta de Galicia, Spain, 2006) to either DDN-plus passive stretching (DDN group) or only passive stretching (control group). A total of 128 participants completed all assessments.

Both treatment programmes (DDN or control) lasted 2 weeks and sessions were conducted twice a week (with 3 days between consecutive sessions), involving a total of 4 treatment sessions. The primary outcome measure was pain intensity. Secondary outcomes were PPT over every active MTrP in the trapezius (all 3 divisions), levator scapulae, splenius cervicis, and multifidi muscles; neck active ROM, neck strength, and neck perceived disability.

2.4. Assessment and data collection

A trained physical therapist with more than 15 years of experience in the diagnosis and treatment of MTrPs was responsible for the physical examination and for entering outcome data on a data sheet. This physical therapist performed the initial and all 6 follow-up assessments of all participants, and remained blinded to group allocation. Participants were instructed to not reveal their group allocation.

In addition, the physical therapists who performed the DDN and who treated the control group assessed participant's pain intensity values before each session so that in case their pain intensity was rated as zero, the intervention was terminated but the follow-up assessments were performed as intended. For the DDN group, the physical therapist who performed the DDN recorded any collateral or adverse effects that may result from the DDN. ^{12,38,54}

2.4.1. Outcome measurement time points

Every outcome was measured at baseline (A0), after the second treatment session (A1—a week after A0), after finishing the intervention (A2—3 weeks after A0), and at follow-up appointments at 15, 30, 90, and 180 days after A2 (A3, A4, A5, and A6, respectively). All outcomes were measured in the same manner across the 6-month study period.

2.4.2. Myofascial trigger point assessment

The diagnosis of active MTrPs was based on the major criteria proposed by Simons et al. ⁸⁶ (**Table 1**). The trapezius, levator scapulae, and splenius cervicis muscles are easily identified. All essential diagnostic criteria for the diagnosis of their MTrPs were present. ⁸⁶ Because of their deep location, MTrPs in the multifidi muscles are more difficult to diagnose. Participants were in the supine position to facilitate optimal relaxation of the overlying muscles. The finding of a painful deep hardness when rubbing the muscle in a longitudinal direction halfway between the spinous and transverse processes ⁸⁶ was considered indicative of the possible location of an MTrP. As stated by the diagnostic criteria proposed by Simons et al., ⁸⁶ the finding of a taut band is not

considered essential in nonaccessible muscles. In the multifidi muscles, the diagnosis of active MTrPs was made when the subjects presented with exquisite spot tenderness on deep palpation, with recognition of the current pain complaint with 10-second pressure, and a painful limit on cervical flexion.

Each active MTrP marked with a permanent dermographic pencil (Richard-Allan Marking Surgical Pen; Aspen Surgical, United Kingdom) was mapped and described on a body chart with anatomical references before covering it with tape (Leukotape sport; BSM Medical GmbH, Germany) so that in case the mark disappeared at follow-up assessments, both DDN and PPT measurements were performed on the same point throughout the study.

2.4.3. Pain intensity (primary outcome)

The participants reported their current pain intensity using a 100-mm visual analogue scale (VAS) consisting of a 100-mm horizontal line with pain descriptors marked "no pain" on the left side and "the worst imaginable pain" on the right side. ⁷⁵ A minimal detectable change of 15 mm is required and a change over 24 mm is considered to be clinically meaningful in subjects with nonspecific neck pain. ⁶¹ The reproducibility and validity of pain intensity rated on a VAS⁷⁵ have been documented in other studies.

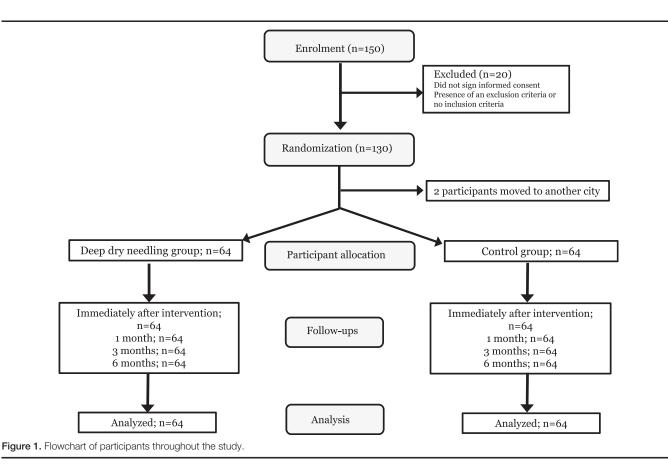
2.4.4. Pressure pain threshold

The PPT was used to measure mechanical hyperalgesia of every active MTrP. The PPT was recorded in kg/cm² using an analogue algometer (Wagner Instruments, Greenwich, CT) with a surface area at the round tip of 1 cm². 34,74 The pressure of compression was

increased gradually at a speed of approximately 1 kg·cm⁻²·s⁻¹. To standardise the speed of application, the researcher responsible for this measurement practiced, 1 week before the study, increasing the pressure linearly to 5 kg/cm² over 5 seconds according to the method recommended by others.³⁴ The participant had to say "yes" as soon as pain or discomfort appeared, and just in that moment the compression was stopped. At each MTrP, 3 repetitive measurements were recorded with an interval of 30 seconds between each of the measurements. The highest reading was discarded, and the mean of the 2 remaining readings was used for analysis. ^{32,87} 1.13 kg/cm² is the minimum detectable change required for the result of PPT to be clinically meaningful in subjects with neck pain. ⁹⁵ The reproducibility and validity of PPT^{34,74} have been documented in previous studies.

2.4.5. Neck active range of motion

Active range of neck flexion and extension, rotation, and side-bending were recorded by means of a Cervical Range of Motion (CROM) goniometer (Performance Attainment Associates, Roseville, the Netherlands). ⁹⁸ The participant was seated with a straight back leaning against the back of a chair, wearing the CROM goniometer over the head, and was asked to perform active flexion, extension, rotation (left and right), and side bending (left and right). The participants were instructed to stop at the point where pain symptoms began, or otherwise to continue to the fullest extent of their mobility. Each movement was recorded 3 times, and the mean was calculated after discarding the lowest reading. This method³⁵ has demonstrated good validity and reproducibility. ⁴ A minimal detectable change of 10° is required for the result of ROM in subjects with neck pain. ³⁵



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2.4.6. Neck muscles strength

Neck muscle strength was measured using a digital dynamometer (MicroFET 2 MT Digital Handheld Dynamometer; Hoggan Health Industries, West Draper, UT); test–retest reliability and accuracy of this device is excellent, ^{10,44} being more sensitive to small differences in muscle strength than manual muscle testing. ⁹¹ The participant was seated with the back against a chair and was asked to perform maximal cervical isometric contractions in every measured direction (flexion, extension, right and left rotation, and right and left side bending). ⁹² Three measurements were recorded for each direction and consisted of a maximal isometric contraction for 3 seconds with a rest period of 10 seconds between contractions to minimise variability due to fatigue. ²⁶ A 15-Newton change in force was considered by the study research team to be clinically meaningful.

2.4.7. Neck disability

The level of perceived neck disability was measured with the Neck Disability Index (NDI) score. The NDI is a self-report instrument for the assessment of the condition-specific functional status of

subjects with neck pain with 10 items including pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Each section is scored on a 0-to-5 rating scale, in which 0 means "no pain" and 5 means "worst imaginable pain." All the points are summed to a total score. The questionnaire can be interpreted as a raw score, with a maximum score of 50 points, or as a percentage (100%). Disability categories for the NDI are 0 to 4 points (0%-8%), no disability; 5 to 14 points (10%-28%), mild; 15 to 24 points (30%-48%), moderate; 25 to 34 points (50%-64%), severe; and 35 to 50 points (70%-100%), complete. The NDI has been shown to have a high degree of test—retest reliability, internal consistency, and an acceptable level of validity being sensitive to changes over time. ²⁴ A 10-point change is required for the result to be clinically meaningful. ⁹⁹

2.4.8. Other variables

In the baseline assessment (A0), demographic and identification data were collected: age, sex, occupation, family status, body mass index, sport practice frequency, and history related to the problem, such as the duration of symptoms and previous trauma.

Comparison between randomized groups at baseline.

Outcome	Contro	l group		DDN group				
	N	Mean or %	SD	N	Mean or %	SD	Groups difference	
Profession	64	83%		64	86%		0.03	
Age	64	52	16.6	64	48	15.7	4	
Osteopenia	64	0.8%		64	0.8%		0	
Osteoporosis	64	3.1%		64	1.6%		0.015	
Arthrosis	64	21.1%		64	20.3%		0.008	
Body mass index	64	26.3	4.3	64	26.2	4.6	0.1	
Sex	64	14.8		64	21.9		7.1	
Pain VAS A0	64	5.1	1.4	64	5.1	1.6	0	
ROM rotation A0	64	106.6	18.1	64	107.8	22.5	1.2	
ROM side bending A0	64	59.9	13.5	64	63.1	16.2	3.2	
ROM flexion-extension A0	64	99.8	18.9	64	102	16.6	2.2	
Strength right rotation A0	64	85.4	29.3	64	84.6	32.5	0.8	
Strength left rotation A0	64	87.6	32.8	64	85.3	33.1	2.3	
Strength right side bending A0	64	88.9	29.9	64	89.7	35.6	0.8	
Strength left side bending A0	64	87.4	31.2	64	86.3	33.8	1.1	
Strength flexion A0	64	86.5	36.3	64	91.7	47.2	5.2	
Strength extension A0	64	93.7	35.4	64	97.8	35.9	4.1	
Pressure pain threshold (PPT) A0 right trapezius	54	2	0.6	59	2.1	0.7	0.1	
PPT A0 left trapezius	53	2.1	0.8	54	2.1	0.8	0	
PPT A0 right levator	39	2	0.7	40	1.9	0.6	0.1	
PPT A0 left levator scapulae	35	2.1	0.7	29	1.9	0.8	0.2	
PPT A0 right splenius cervicis	36	1.9	0.8	24	2	0.7	0.1	
PPT A0 left splenius cervicis	36	2	0.8	25	1.9	0.8	0.1	
PPT A0 right multifidi	48	2.4	0.7	41	2.4	0.7	0	
PPT A0 left multifidi	45	2.4	0.7	33	2.5	0.8	0.1	
Latent myofascial trigger points A0	64	14.1%		64	21.9%		0.078	

Values are numbers (percentages) unless otherwise stated.

A0, baseline assessment; ROM, range of motion.

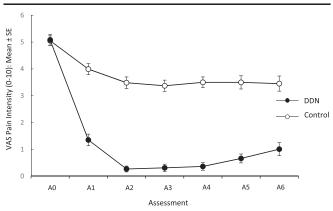


Figure 2. Evolution of pain intensity throughout the study in both groups. Comparison of means of pain intensity scores (VAS) at baseline (A0), after 2 sessions at 7 days after A0 (A1), posttreatment at 3 weeks after baseline (A2), at 15 days after A2 (A3), at 30-day follow-up after A2 (A4), at 3-month follow-up (A5), and at 6-month follow-up (A6). Assessments: A0: baseline, A1: after 2 sessions, A2: post-intervention at 3 weeks after baseline, A3: 15 days after A2, A4: 30-day follow-up after A2, A5: 3-month follow-up, A6: 6-month follow-up. DDN, deep dry needling; VAS, visual analogue scale.

2.5. Sample size estimation

The study was designed to detect a between-group difference of 21.9 mm in pain intensity scored on the VAS. This a priori sample size estimation was calculated according to the findings of a previous study, 19 which used a similar intervention in 44 subjects obtaining SD (dry needling group [n = 22]: 16.09 mm; control group [n = 22]: 29.87 mm). The specifications were: a power of 95%, an alpha level of 0.05, and a possible loss to follow-up of up to 20%. Therefore, a total of 130 participants (65 participants per group) were recruited. To increase the precision of the effects of interventions, the estimates used to calculate our sample size were lower than those suggested, because 24 mm is considered to be clinically meaningful in chronic nonspecific neck pain subjects. 61 A higher between-group difference would have dramatically reduced our sample size, 72 but this is one of the major limitations of previous studies, 63,73 which we tried to avoid in our study. Sample-size estimation was made using the statistical program EPIDAT 3.1 (Xunta de Galicia, Spain, 2006).

2.6. Interventions

Each group had a single physical therapist who performed all interventions, and they were the only study members aware of group allocation. The 2 physical therapists had more than 10 years of experience each in the clinical use of DDN and passive stretching and received special training before the study in how to perform the passive stretch of the trapezius, levator scapulae,

splenius cervicis, and multifidi muscles, so that both groups received the same passive stretching. This guaranteed blinding and safety when applying the techniques. ⁸⁰ If participants no longer reported pain (VAS = 0) before the end of the 4 scheduled physical therapy sessions, treatment was terminated, while maintaining all follow-up examinations as planned from the beginning.

2.6.1. Deep dry needling

The intervention included DDN of every active MTrP found in trapezius (all 3 divisions), cervical multifidi, splenius cervicis, and levator scapulae muscles, using a 40- × 0.32-mm acupuncture needle with guided tube (ASP. A1040P; Agu-punt S.L. acupuncture-physical therapy, Barcelona, Spain). The treatment procedure included hand washing, clean latex-free examination gloves, and cleaning the participants' skin with an alcohol swab before treatment. The DDN was performed following the procedures as described for each muscle by Simons et al.86 Once the needle was inserted into the active MTrP, previously marked by the blinded assessor, 4 to 5 local twitch responses (LTRs) were obtained by performing multiple rapid insertions of the needle, in and out of the MTrP, in a way similar to Hong's fastin and fast-out technique.⁴⁷ Then, the needle was withdrawn, haemostatic compression was applied, and passive stretch was performed on the needled muscles.

2.6.2. Passive stretching

A passive stretch of splenius cervicis, cervical multifidi, levator scapulae, and all 3 divisions of the trapezius muscles was applied whenever they showed active MTrPs. The stretch was applied in the positions described by Simons et al. ⁸⁶ During the stretch, the physical therapist took up the slack, avoiding pain elicitation, maintaining the tension for 4 seconds, and releasing the tension for 8 seconds; this cycle was repeated 3 times, completing a stretch of 36 seconds. ¹⁹ This stretch was repeated 4 times.

3. Statistical analysis

Stata v.12 and R v.3 was used for the statistical analysis. Descriptive statistics were calculated to describe baseline data. T-tests were conducted to determine whether the 2 groups differed on the demographic variables (age and sex) and day 0 (preintervention) characteristics: body mass index, hours of physical activity per week, and A0 pain, neck ROM, PPT, neck muscle strength, and neck disability (outcomes, dependent variables). A 2 \times 7 factorial design analysis of variance with repeated measurements was conducted to analyze dependent variables over time. Bonferroni and Dunn tests were used for

Table 3 Intergroup comparison of pain values (results expressed as mean [SD]).

VAS Control group		DDN gro	oup		Intergroup comparison T-student				
	N	Mean	SE	N	Mean	SE	Mean difference	P	95% CI
A1 - A0	64	-1.06	0.16	64	-3.73	0.22	2.67	0.00000	2.14-3.20
A2 - A0	64	-1.57	0.17	64	-4.81	0.2	3.24	0.00000	2.72-3.77
A6 - A0	64	-1.60	0.25	64	-4.08	0.25	2.48	0.00000	1.77-3.18

Comparison of means of pain intensity rated on a visual analogue scale (VAS) showing the effect in each group after 2 sessions at 7 days after A0 (A0 — A1), postintervention effect at 3 weeks after baseline (A0 — A2) and the effect at 6-month follow-up (A0 — A6).

DDN, deep dry needling; VAS, visual analogue scale.

A1 — A0: effect of 2 sessions; A2 — A0: effect after intervention (4 sessions); A6 — A0: 6-month follow-up effect.

multiple comparisons. Differences between the groups were analyzed using the Student ttest (for PPT, ROM, muscle strength, and NDI scores) to assess the relationship between group status (DDN/control). The association between dichotomous variables was examined using the Fisher exact test.

To examine for the possible confounding effects of other factors such as age, sex, arthrosis, osteopenia, or osteoporosis, multiple linear regressions were run, taking as the dependent variables A2 - A0 or A6 - A0 difference, and introducing the potential confounders in successive runs. To identify potential effect modifiers, the interaction variables were created as a product of the previous ones. These new variables were incorporated in the regression model in a step-by-step way.

4. Results

Figure 1 shows the flow of the participants throughout the study. A total of 128 participants finished the study, 64 in each group. The mean number of treatments (SD) received was 3 (1) in the DDN group and 3.6 (0.77) in the control group. Two dropouts were registered because they moved to another city. Table 2 presents the baseline demographics and descriptive preintervention statistics.

4.1. Effects of interventions

In the DDN group, 12 participants (19%) received 3 treatment sessions, 37 participants (58%) received 2 sessions, and 3 participants (5%) only 1 session indicating that these subjects reported complete relief of their symptoms and did not require the fourth scheduled session. In the case of the control group, 15 participants (23%) reported complete relief of neck pain after 2 sessions, while the remaining participants required all 4 sessions of treatment and did not reach complete recovery of their complaints.

The subjective pain intensity (Fig. 2, Table 3) decreased significantly (P < 0.00001) after treatment in both groups: A2 – $A0 = -4.81 \pm 0.20$ in the DDN group and -1.57 ± 0.17 in the control group, with a larger effect (3.24 units) in the DDN group (95% confidence interval 2.72-3.77; P < 0.00000). The effect was maintained throughout the 6-month follow-up: A6 - A0 = -4.08 ± 0.25 in the DDN group and -1.60 ± 0.25 in the control group, but the effect was again larger 2.48 units in the DDN group (95% confidence interval 1.77-3.18; P < 0.00000).

Even after just 2 sessions (at A1), pain intensity decreased significantly in both groups, but in the DDN group, the reduction in pain intensity was 2.67 units larger than in the control group (95%

Table 4	
Evolution of pressure pain thresholds	(PPT) throughout the study in both groups (results expressed as mean [SE]).

PPT	Contro	l group		DDN g	roup		Mean difference	P	95% CI
	N	Mean	SE	N	Mean	SE			
Right trapezius									
A1 — A0	54	0.59	0.09	59	1.87	0.21	1.28	0.00000	1.73 to 083
A2 - A0	54	0.98	0.13	59	2.8	0.23	1.82	0.00000	2.33 to 1.29
A6 — A0	54	1.11	0.14	58	2.28	0.27	1.17	0.00025	1.78 to 0.56
Right levator									
A1 - A0	39	0.63	0.13	39	1.56	0.26	0.93	0.00248	1.51 to 0.34
A2 - A0	39	0.69	0.13	40	2.64	0.32	1.95	0.00000	2.63 to 1.26
A6 - A0	39	1.05	0.17	40	2.04	0.36	0.99	0.01654	1.80 to 0.19
Right splenius									
A1 — A0	36	0.59	0.13	24	1.29	0.31	0.7	0.04446	1.37 to 0.02
A2 - A0	36	0.66	0.14	24	1.69	0.24	1.03	0.0006	1.59 to 0.47
A6 - A0	36	0.94	0.16	24	0.98	0.25	0.04	0.90362	0.63 to -0.56
Right multifidi									
A1 — A0	48	0.74	0.1	41	2.32	0.26	1.58	0.00000	2.13 to 1.02
A2 - A0	48	1.13	0.18	41	3.3	0.26	2.17	0.00000	2.80 to 1.53
A6 - A0	48	0.91	0.16	40	2.71	0.33	1.80	0.00001	2.54 to 1.08
Left trapezius									
A1 - A0	53	0.67	0.11	53	1.35	0.18	0.68	0.00199	1.10 to 0.25
A2 - A0	53	0.93	0.13	54	2.62	0.23	1.69	0.00000	2.22 to 1.16
A6 — A0	53	1.03	0.14	54	2.13	0.29	1.10	0.00092	1.74 to 0.47
Left levator									
A1 - A0	35	0.7	0.13	27	1.93	0.35	1.23	0.00232	1.98 to 0.47
A2 - A0	35	0.6	0.15	25	3.29	0.43	2.69	0.00000	3.62 to 1.76
A6 — A0	34	0.63	0.14	27	2.58	0.47	1.95	0.00035	2.95 to 0.96
Left splenius									
A1 - A0	36	0.66	0.13	25	1.41	0.28	0.75	0.02025	1.38 to 0.12
A2 - A0	36	0.69	0.16	24	2.33	0.43	1.64	0.00116	2.57 to 0.71
A6 — A0	35	0.96	0.22	25	1.68	0.46	0.72	0.16484	-1.75 to 0.31
Left multifidi									
A1 - A0	45	0.99	0.15	33	2.05	0.26	1.069	0.00094	1.67 to 0.45
A2 - A0	45	1.05	0.17	32	3.22	0.28	2.17	0.00000	2.83 to 1.51
A6 - A0	45	1.13	0.17	33	2.62	0.33	1.49	0.00021	2.23 to 0.74

Comparison of means of PPT showing the effect in each group after 2 sessions at 7 days after A0 (A0 — A1), postintervention effect at 3 weeks after baseline (A0 — A2) and the effect at 6-month follow-up (A0 — A6). A2 - A0: effect after intervention; A6 - A0: 6-month follow-up effect.

CI, confidence interval.

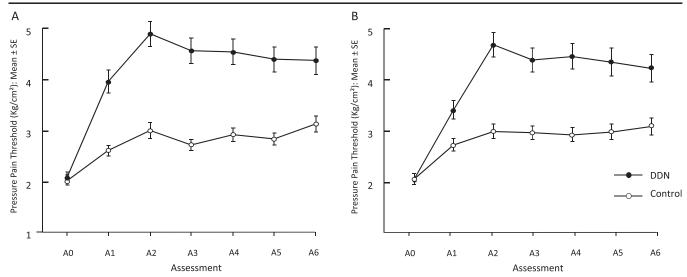


Figure 3. Evolution of pressure pain thresholds (PPT) of the right (A) and left (B) trapezius muscles throughout the study in both groups. Comparison of means of PPT at baseline (A0), after 2 sessions at 7 days after A0 (A1), posttreatment at 3 weeks after baseline (A2), at 15 days after A2 (A3), at 30-day follow-up after A2 (A4), at 3-month follow-up (A5), and at 6-month follow-up (A6). Assessments: A0: baseline, A1: after 2 sessions, A2: post-intervention at 3 weeks after baseline, A3: 15 days after A2, A4: 30-day follow-up after A2, A5: 3-month follow-up, A6: 6-month follow-up. DDN, deep dry needling; PPT, pressure pain threshold.

confidence interval 2.14-3.20; P < 0.00000). The decrease of pain intensity in the DDN group was clinically meaningful⁶¹ at A1, A2, and A6. No relevant interaction of confounding effects existed, in relation to the treatment effects, regarding age, sex, body mass index, hours of work per day, pain, arthrosis, osteoporosis, ostheopenia, or drug consumption in relation with the treatment or the group.

Table 4 presents the PPT data over time for each group, and **Figure 3** illustrates the time course of PPT specifically for the trapezius muscle. In general, the PPT of the other muscles examined showed similar changes over time for each group. For the trapezius muscle, both groups showed a statistically significant increase of PPT after treatment; 2.8 ± 0.23 kg/cm² for the DDN group and 0.98 ± 0.13 for the control group, with a larger effect for the DDN group (1.82 units, 95% confidence interval 1.29-2.33; P < 0.0000). Clinically meaningful results⁹⁵ were seen only in the DDN group. The effect was maintained at the 6-month follow-up: A6 –

A0 = $2.28 \pm 0.27 \, \text{kg/cm}^2$ for the DDN group and 1.11 ± 0.14 for the control group, which means that the effect was $1.17 \, \text{units}$ larger for the DDN group (95% confidence interval 0.56-1.78; P = 0.0003), and again clinically meaningful⁹⁵ for the DDN group but not for the control group. The same significant difference was seen for all other muscles examined except for splenius cervicis, in which no difference was found at the 6-month follow-up (P > 0.05) (**Table 4**).

Neck active ROM (**Table 5**) significantly increased in the DDN group for all movement directions, whereas no significant change was observed for the control group. **Figure 4** shows the change of ROM over time in a representative direction—rotation. All movement directions showed a similar pattern. Active ROM showed a significant improvement after just 2 sessions in the DDN group, and this was maintained until A6. At all measurement points, apart from baseline, the DDN group showed significantly larger neck ROM compared with that of the control group (95% confidence interval 8.2-19.4; *P* < 0.000001).

Table 5

Evolution of neck active range of motion throughout the study in both groups (results expressed as mean [SE]) measured showing the effect in each group after 2 sessions at 7 days after A0 (A0 - A1), postintervention effect at 3 weeks after baseline (A0 - A2), and the effect at 6-month follow-up (A0 - A6).

	Control group			DDN gı	roup		Mean difference	P	95% CI
	N	Mean	SE	N	Mean	SE			
Rotation									
A1 - A0	64	3.03	0.99	64	12.9	1.38	9.02	0.0000	5.13-2.14
A2 - A0	64	4.02	1.46	64	16.1	1.76	12.05	0.0000	7.50-16.6
A6 — A0	64	3.98	1.19	64	17.8	1.78	13.80	0.0000	8.2-19.4
Side bending									
A1 - A0	64	2.86	0.80	64	8.36	1.6	5.5	0.0003	2.55-8.45
A2 - A0	64	4.03	1.04	64	13.09	1.63	9.06	0.0000	5.2-12.9
A6 - A0	64	4.92	1.43	64	13.5	1.69	8.59	0.0002	4.21-12.9
Flexion extension									
A1 - A0	64	3.73	1.21	64	11.8	1.45	8.08	0.0000	4.33-11.8
A2 - A0	64	3.78	1.46	64	17.1	1.64	13.30	0.0000	9.0-17.7
A6 - A0	64	4.98	2.27	64	19.3	1.80	14.28	0.0000	8.5-20.0

A1-A0: effect of 2 sessions; A2-A0: effect after intervention (4 sessions); A6-A0: 6-month follow-up effect. DDN, deep dry needling; ROM, range of motion.

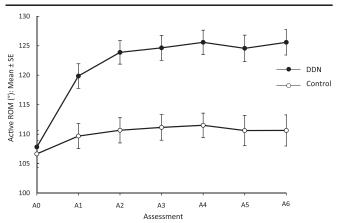


Figure 4. Evolution of neck active range of motion (ROM) in rotation throughout the study in both groups. Comparison of means of degrees at baseline (A0), after 2 sessions at 7 days after A0 (A1), post-treatment at 3 weeks after baseline (A2), at 15 days after A2 (A3), at 30-day follow-up after A2 (A4), at 3-month follow-up (A5), and at 6-month follow-up (A6). Assessments: A0: baseline, A1: after 2 sessions, A2: post-intervention at 3 weeks after baseline, A3: 15 days after A2, A4: 30-day follow-up after A2, A5: 3-month follow-up, A6: 6-month follow-up. AROM, active range of motion; DDN, deep dry needling.

The DDN group also showed greater improvement of neck muscle strength (**Table 6**) for all tested directions compared with the control group. As an example, **Figure 5** presents the findings for right rotation strength. Although no significant change in strength was observed for the control group at any time point, the

DDN group showed a significant increase from the second session, which was maintained until A6. At all measurement points, apart from baseline, the DDN group showed significantly greater neck muscle strength compared with that of the control group (95% confidence interval 22.3-36.6; P < 0.000001). In addition, this increase in strength was clinically meaningful at A1, A2, and A6.

In the case of neck disability (**Fig. 6**), mean values decreased significantly (P < 0.00001) after treatment in both groups: A2 - A0 $= -17.3 \pm 2.06$ in the DDN group and -1.77 ± 0.17 in the control group, with a larger effect for the DDN group (11.9 units, 95% confidence interval 5.49-16.2; P < 0.00000). This effect was maintained at the 6-month follow-up: A6 - A0 $= -18.5 \pm 2.27$ for the DDN group and -8.43 ± 1.84 for the control group. Overall, the effect was 10.1 units larger in the DDN group (95% confidence interval 4.40-17.70; P < 0.00000) (**Table 7**). All the results were clinically meaningful after intervention and at medium (3 months) and long-term follow-up (6 months) for the DDN group as opposed to the control group. 18,61,62,95,99

Soreness³⁵ and local haemorrhages at the needling site³⁵ occurred after DDN in some cases, but they resolved within 1 week. No collateral effects or adverse effects were reported by participants or observed by the physical therapist after DDN.^{12,54}

5. Discussion

Deep dry needling with passive stretching applied to participants with chronic nonspecific neck pain attributed to MPS was associated with better and clinically meaningful results for pain, mechanical hyperalgesia, range of cervical motion, neck muscle

Table 6 Evolution of neck strength throughout the study in both groups (results expressed as mean [SE]).

Strength	Contro	l group		DDN gı	roup		Mean difference	P	95% CI
	N	Mean	SE	N	Mean	SE			
Right rotation									
A1 - A0	64	2.11	1.19	64	17.9	0.03	15.75	0.0000	11.1-20.4
A2 - A0	64	6.34	1.38	64	27.3	2.57	21.0	0.0000	15.2-28.8
A6 — A0	64	5.39	2.07	64	34.8	2.93	29.45	0.0000	22.3-36.6
Right side bending									
A1 - A0	64	2.34	1.47	64	14.9	0.09	12.67	0.0003	5.90-19.4
A2 - A0	64	3.59	1.43	64	24.9	3.31	25.4	0.0000	18.7-28.4
A6 - A0	64	5.44	2.04	64	30.9	2.51	13.80	0.0000	8.2-32.2
Flexion									
A1 - A0	64	2.38	1.53	64	18.0	2.56	15.66	0.0000	9.76-21.6
A2 - A0	64	4.89	1.70	64	31.2	3.40	26.32	0.0000	18.8-33.8
A6 — A0	64	7.56	2.85	64	42.9	3.91	35.34	0.0000	25.8-44.4
Left rotation									
A1 - A0	64	0.55	1.32	64	18.5	2.29	17.92	0.0000	12.7-23.1
A2 - A0	64	4.20	1.34	64	28.5	2.67	24.34	0.0000	18.4-30.2
A6 - A0	64	5.16	2.06	64	35.3	2.76	30.19	0.0000	23.4-37.0
Left side bending									
A1 - A0	64	0.94	1.55	64	14.8	2.93	13.84	0.0001	7.23-20.4
A2 - A0	64	3.89	1.24	64	25.2	3.51	21.31	0.0000	13.9-28.7
A6 — A0	64	3.84	2.57	64	31.9	2.62	27.41	0.0000	20.1-34.7
Extension									
A1 - A0	64	4.67	1.71	64	17.7	2.24	13.05	0.0000	7.47-18.7
A2 - A0	64	5.98	2.01	64	33.9	3.73	27.92	0.0000	19.5-36.3
A6 - A0	64	5.58	2.94	64	42.0	4.09	34.4	0.0000	44.5-19.4

Comparison of means in Newtons measured showing the effect in each group after 2 sessions at 7 days after A0 (A0 - A1), postintervention effect at 3 weeks after baseline (A0 - A2), and the effect at 6-month follow-up (A0 - A6).

DDN, deep dry needling; CI, confidence interval.

A1 - A0: effect of 2 sessions; A2 - A0: effect after intervention (4 sessions); A6 - A0: 6-month follow-up effect.

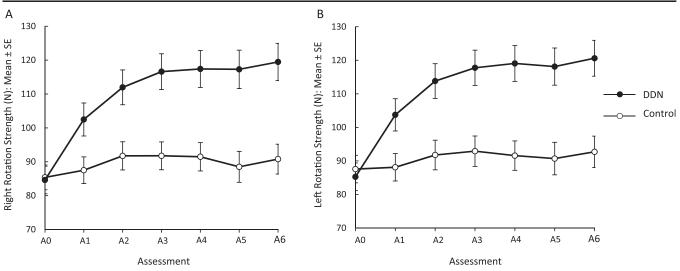


Figure 5. Evolution of neck right and left rotation strength throughout the study in both groups. Comparison of means of Newton at baseline (A0), after 2 sessions at 7 days after A0 (A1), posttreatment at 3 weeks after baseline (A2), at 15 days after A2 (A3), at 30-day follow-up after A2 (A4), at 3-month follow-up (A5), and at 6-month follow-up (A6). Assessments: A0: baseline, A1: after 2 sessions, A2: post-intervention at 3 weeks after baseline, A3: 15 days after A2, A4: 30-day follow-up after A2, A5: 3-month follow-up, A6: 6-month follow-up. DDN, deep dry needling; VAS, visual analogue scale.

strength, and neck disability when compared with passive stretching only (control group) in the short-term and at 6-month follow-up.

Simons et al. ⁸⁶ hypothesized that the mechanical disruption of the contraction areas forming an MTrP by the needle was the critical therapeutic factor to account for the success of DDN in this condition. The contraction areas are believed to be located in dysfunctional motor endplates. ⁸⁶ One study showed that multiple insertions of a needle in the endplate zone of the levator auris longus muscle of mice induce a neuromuscular injury that mechanically affects muscle fibres and motor endplates. ²⁹ It is conceivable that the precise location of the MTrP with the needle, confirmed by LTRs elicitation, ²⁹ could contribute to the changes in the dysfunctional nature of the fibers and motor endplates that make up the MTrP, thus accounting for the beneficial results observed with DDN. The effect of DDN could also be attributed to an increase in microcirculation ¹⁶ and the lavage of sensitizing

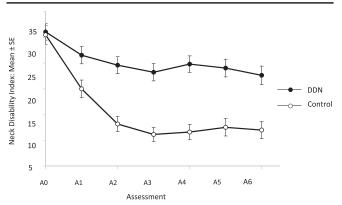


Figure 6. Evolution of neck disability throughout the study in both groups. Comparison of Neck Disability Index scores at baseline (A0), after 2 sessions at 7 days after A0 (A1), posttreatment at 3 weeks after baseline (A2), at 15 days after A2 (A3), at 30-day follow-up after A2 (A4), at 3-month follow-up (A5), and at 6-month follow-up (A6). Assessments: A0: baseline, A1: after 2 sessions, A2: post-intervention at 3 weeks after baseline, A3: 15 days after A2, A4: 30-day follow-up after A2, A5: 3-month follow-up, A6: 6-month follow-up. DDN, deep dry needling; NDI, Neck Disability Index.

substances in the zone, 81,85 which would decrease both peripheral and central sensitization, 30 or breaking up of the vicious cycle maintaining the MTrP. 47,84,85 However, other factors (eg, patient expectation about DDN) may have had an influence on the outcomes.

It is known that the presence of MTrPs is associated with hyperalgesia, weakness, and restricted ROM of the muscles harbouring them. ⁸⁶ Patients with chronic neck pain typically present with reduced ROM and strength, ^{17,22,33,92,93} which are related to disability. ⁷⁷ Elimination of the MTrPs might explain the increase in PPT, neck ROM, and strength after treatment as seen in previous studies, ^{19,64,71} in addition to the improvement in neck disability found in the current study.

Muscle stretching techniques have long been proposed as an effective technique for the treatment of MTrPs. ⁸⁶ The therapeutic goal is to restore muscle length, which should lead to increased active and passive ROM⁵⁷ but that was not the case in our study as the effects on ROM were weak with stretching. Edwards et al. ³² stated that stretching without prior deactivation of the MTrP could increase its sensitivity, which actually could partially explain the superiority of combining DDN with stretching in our DDN group.

The beneficial results observed for neck strength are in line with previous studies, in which facilitation of motor function was observed after DDN. ^{28,60} The high prevalence of MTrPs in people with chronic neck pain ^{20,21,65} and the fact that the needling treatment of MTrPs increased strength raises the question of the possible contribution of MTrPs to the weakness observed in these patients. Previous research has shown that passive stretching does not affect strength, ⁶⁸ which fits with the current results for the control group.

Other studies have described the effects of DDN in different neck pain populations, and although most studies are in agreement on the positive effects of DDN in MTrPs management regarding pain, PPT, or disability, most have methodological issues regarding the proper blinding of assessors and/or patients, \$5.37,48,55,56,58,63,66,73,87,90 use of a controversial sham needling, \$5.56,73,87,90 lack of follow-up, \$5.19,37,48,55,56,58,63,73,87,90 lack of description of the LTRs obtained by DDN, or the DDN technique itself, \$5.38,55,56,58,63,73 lack of a control group, \$5.37,58,63,66

Evolution of the Neck Disability Index score throughout the study in both groups (results expressed as mean [SE]).

Disability Control group			DDN gr	oup		Comparison intergro	Comparison intergroup T-student			
	N	Mean	SE	N	Mean	SE	Mean difference	P	95% CI	
A1 — A0	64	-4.52	1.44	64	-10.5	2.31	5.98	0.04	0.3-11.6	
A2 - A0	64	-6.47	1.77	64	-17.3	2.06	11.9	0.0001	5.49-16.2	
A6 - A0	64	-8.43	1.84	64	-18.5	2.27	10.1	0.0006	4.4-15.7	

Comparison of means in Newtons measured showing the effect in each group after 2 sessions at 7 days after A0 (A0 - A1), postintervention effect at 3 weeks after baseline (A0 - A2), and the effect at 6-month follow-up (A0 - A6). A1 - A0: effect of 2 sessions; A2 - A0: effect after intervention (4 sessions); A6 - A0: 6-month follow-up effect DDN, deep dry needling.

limited number of treatments, 5,37,55,58,63,66,73,90 difficulty translating the results to the clinical setting because of an overly analytical approach, 37,64,67,74,91 lack of a power analysis to justify sample size, 37,55,56,58,66,73,90 small sample size, 19,37,55,56,58,63,66,73,87,90 and the lack of an analysis or a discussion about the clinical meaningfulness of the results. 5,37,55,56,58,63,66,73,87,90

As an example, the study by Llamas-Ramos et al. 63 compared the effect of DDN and manual therapy in participants with chronic mechanical neck pain in the short term. This trial compared 2 different groups of MTrP techniques applied to a single MTrP located in the upper trapezius: DDN technique in one group and 3 different manual therapy applications including pressure release, taut band manual stretch, and passive therapeutic stretch in the other group. Contrary to our study, Llamas-Ramos et al. 63 were not able to find clinically relevant within-group differences or significant between-group differences, except in PPT, favouring the DDN group. There are several methodological differences between the studies that could account for this: (1) In the study by Llamas-Ramos et al., 63 DDN provoked at least 1 LTR, but there was no indication of whether this was the only elicited LTR or, otherwise, the number of LTRs that occurred. This is an important issue because the efficacy of DDN seems to be correlated with the LTRs. 48 If only 1 LTR was elicited, it may have been clinically insufficient to obtain good results. Recent research shows that the size of the effect of DDN on MTrPs increases with the number of LTRs obtained; (2) The number of sessions applied in our study was 4, whereas it was just 2 in the study of Llamas-Ramos et al., ⁶³ which may not be sufficient to obtain significant results in a chronic neck pain population; (3) In our study we treated as many active MTrPs found bilaterally in 4 relevant muscles,²⁰ whereas in their study they treated only 1 MTrP located in just 1 muscle, the upper trapezius unilaterally. Prevalence studies of MTrPs in chronic nonspecific neck pain show that muscle involvement is much higher than just one muscle, 20 on just one side, and bilateral pain is very common in neck pain⁹; (4) We followed up our subjects for 6 months, whereas Llamas-Ramos et al. did a short-term follow-up of just 2 weeks. Some other methodological issues including the young age of the sample (31 ± 3 years), whose source is neither mentioned nor established, the lack of a control group, concerns about the proper marking of the MTrP so as to be sure that treatments and assessments were done in the same location in consecutive visits, could further explain the differences between studies.

This study shows that DDN is a safe form of treatment for chronic nonspecific neck pain and offers clear clinical advantages over passive stretching in the reduction of pain and improvement of mechanical hyperalgesia, active cervical ROM, and cervical muscle strength and function. Deep dry needling treatment improves the clinical signs and symptoms of patients with chronic nonspecific neck pain, achieving very meaningful clinical differences. However, the study is limited by the duration of the follow-up (only up to 6

months after intervention). Nevertheless, most studies on chronic neck pain treatment^{1,2,8,9,13,14,42,43,62,78,82} by DDN focus on its immediate effects, ^{19,27,55,56,91} or use only a very short-term followup. In this study, we performed 2-week, 1-month, 3-month, and 6month follow-ups, which allowed us to monitor the evolution of pain and the effect of DDN over a longer time.

A possible drawback of this study is the difficulty of controlling external interventions, such as self-medication of analgesics, anti-inflammatories, muscle relaxants, or other drugs. We tried to avoid this by reminding and instructing all participants about this at each assessment visit. In addition, at every treatment session, participants were asked to fill out a form detailing whether they had had any drug or physical therapy treatment since the last visit. No additional external interventions were registered in our study.

The fact that passive stretching of muscles was administered by 2 different physical therapists could be another possible drawback. However, consensus and training sessions with reconciliatory meetings were performed to ensure that both physical therapists applied the passive stretch in the same way.

Further limitations could have been the possible loss of MTrP locator marks, which was avoided by remarking the location with a permanent felt-tip marker and immediately covering the mark with adhesive tape at every visit to prevent its erasure. In addition, MTrPs were mapped and described on a body chart with anatomical references. In addition, treatment time was slightly different between groups as the subjects in the DDN group received an additional procedure and spent more time with the physical therapist than did the subjects in the control group. This may have had a placebo effect thus influencing outcomes.

In summary, DDN can help to relieve chronic nonspecific neck pain. Needling produces a decrease in pain, an increase of PPT, an increase of active neck ROM, an increase of neck muscle strength, and improved cervical function in patients with chronic nonspecific neck pain. These results were maintained after a 6month follow-up and would support the use of DDN in the management of chronic nonspecific neck pain attributed to MPS.

Conflicts of interest statement

The authors have no conflicts of interest to declare.

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M. Pérez-Muñoz, I. Fuentes-Gallardo. Assessment of the participants: E. Cerezo-Téllez (blind assessor). Data analysis and interpretation: L. Prieto Valiente (blind analyst), E. Cerezo-Téllez, M. Torres-Lacomba, O. Mayoral-del-Moral, and E. Lluch Girbés. Collection and assembly of data: O. Mayoral-del-Moral. Manuscript writing: E. Cerezo-Téllez, M. Torres-Lacomba, O. Mayoral-del-Moral, E. Lluch Girbés, and D. Falla. Manuscript revising: E. Cerezo-Téllez, M. Torres-Lacomba, O. Mayoral-del-Moral, L. Prieto Valiente, E. Lluch Girbés, and D. Falla.

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