

## Dry Needling is an Effective Short-Term Therapeutic Choice for Patients with Shoulder and Nocturnal Pain

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### Abstract

The clinical cluster of pain, limited range of motion and dysfunction usually associated to shoulder problems is frequently accompanied by nocturnal pain in patients with rotator cuff disease, adhesive capsulitis, and calcific tendinitis and may aggravate the shoulder disorder. Night pain and poor quality of sleep influence the variable perceived shoulder pain and shoulder function, affecting the wellbeing of patients and influencing the bio psychosocial aspect. A relationship exists between the severity of sleep disturbance in proportion to the intensity of the shoulder pain and shoulder dysfunction.

**Keywords:** Shoulder pain; Musculoskeletal sensitization; Hypersensitivity; Deep dry needling

### Introduction

Pain and sleep disturbance are two important complaints that interact in ways that remain poorly understood [1-5]. An exacerbation of mechanical hypersensitivity and changes in sleep-wake behaviour has been demonstrated in experiments in which sleep fragmentation were combined with musculoskeletal sensitization. These effects result from the synergistic interactions between sleep fragmentation and musculoskeletal sensitization, and do not result from sleep fragmentation or from musculoskeletal sensitization per se and isolate. It seems that sensitization in skeletal muscles plays an important role in sleep behaviour [6].

There are several physiotherapeutic treatments for shoulder pain [7,8]. Several studies have emphasized the deactivation of myofascial trigger points (MTrP) as an effective technique in the treatment of shoulder pain [9-12] and a decreased number of MTrPs has been reported after an effective physiotherapy personalized treatment [10,13]. Currently, no studies have focused on the reduction of night pain in the treatment of shoulder pain.

Deep dry needling (DDN) is recognized as an effective intervention targeting the treatment of MTrPs [14-17] in several pain syndromes. Trigger point deep dry needling (DDN) intervention (repeated needle insertion) has the objective of deactivating (removing the peripheral source of persistent nociceptive input) the trigger point via mechanical disruption on the contraction knots stretching the contracture sarcomere, [18] and altering the chemical milieu of the trigger point as a region accumulating multiple sensitized nociceptors, after initially causing a local twitch response [19].

The aim of the parent study was to investigate the effectiveness of DDN in addition to personalized, evidence-based physiotherapy treatment versus personalized, evidence-based physiotherapy treatment alone in the treatment of non-specific shoulder pain [13].

Nocturnal pain prevalence found in this parent study was high (68.33%). No differences were found in the variables considered (pain, range of motion and function); only changes indicated a slight between-group difference in nocturnal pain improvement at post-treatment favouring the personalized treatment-plus-dry needling group (odds ratio=0.41; confidence interval, 0.17,0.99), but not at 3-month follow-up.

Our objective in this sub-study is to examine the effect of DDN in patients with nocturnal pain, and whether adds benefits on physical variables such as perceived pain and function, in a jointly manner.

### Methodology

#### Design overview, setting and participants

This research is a sub-study derived from a previously published RCT Registration ISRCTN Number 30907460, whose protocol and results have previously been published [20,13]. For this sub-study, shoulder pain patients included in the RCT/Study [20] who presented with nocturnal pain (determined according to response to the question on having nocturnal pain: yes/no) were considered. The sample for the parent study met the following inclusion criteria: patients over the age of 18, having nonspecific shoulder pain considered by the General Practitioner to be consistent with rotator cuff (RC) tendinopathy or subacromial impingement syndrome (SIS), and having a range of movement greater than 50% (90°) of full range (180°) of flexion, abduction or scapular plane elevation.

The exclusion criteria were prior surgery for subacromial syndrome, disability, pain, or sudden loss of strength after an injury that suggested another condition; glenohumeral instability; symptoms that suggested a systemic disease; impossibility of attending intervention sessions or refusal to participate; or, in the researcher's judgment, any illness or condition that might interfere with trial completion, or harm the patient as a result of participation.

Patients were randomized into two parallel groups: A control group receiving personalized (PT), evidence-based physiotherapy treatment and an intervention group receiving, in addition to this personalized treatment, treatment of inactivation of the MTrP via deep dry needling (PT+DDN). Parallel randomized clinical trials with follow up were carried out three months following treatment completion.

The patients provided their informed consent to participate in the study. This study was carried out in primary health care centres in Zaragoza, Spain. As the patients were included in the study according to the clinical symptoms that they presented, and to confirm the diagnosis, 91% of the sample underwent a diagnostic imaging test (ultrasound) and 50% underwent a magnetic resonance image (MRI).

A patient was considered to have withdrawn from the trial if he/she withdrew their informed consent, if the researcher felt that he /she should withdraw from the study for safety reasons or if the researcher felt it to be in the patient's best interest.

Sample-size calculation was based on the clinically important improvement of 1.5 points on a 0-to-10 visual analogy scale (VAS) for pain, with a standard deviation of 2 points [21]. Assuming a 95% confidence interval and power of 90%, a SD=2 and a minimal difference=1.5, the resulting sample size that would enable us to analyse the final variable consisted of 76 individuals. As an attrition rate of 10% might be expected, the final expected number of patients for recruitment was 86. This number was exceeded, recruiting 120 subjects to ensure the reliability of the study and taking into account the prevalence of this symptomatology. The present sub-study sample consisted of 82 patients (68.33%) who presented nocturnal pain. The protocol did not include any interim analyses or stopping rules.

## Randomization and interventions

Patients were admitted by general practitioners of the primary care centres between 2008 and 2010. Verification of the inclusion and exclusion criteria was carried out and afterwards, the informed consent form was signed.

Participants were randomly assigned to one of two treatment groups. The sequence of randomization, which was concealed throughout the study, was generated using a computer randomization program. Group assignment was carried out by an independent researcher. Due to the nature of the study, it was impossible to maintain blindness of the physical therapist and patient, but the sequence was hidden to all study participants and all assessments were performed by a blinded evaluator in order to ensure the internal validity of the study. The result of the randomization was communicated to the physiotherapist who implemented the treatment once the patient had been included in the study and had been assessed at baseline.

All participants underwent a clinical examination process beginning with a thorough background history, followed by a physical examination of the shoulder girdle [22-24]. Based on this baseline evaluation, the most appropriate personalized and based-evidence manual therapy treatment was planned.

Ten (10) sessions were conducted in the control group, consisting of 30 minutes per session and distributed twice weekly. Subjects assigned to the control group underwent a Personalized physical therapy Treatment (PT) which was based on personalized and individualized manual therapy techniques after physical evaluation [23-25] and based on patient state [22,26-29].

Subjects assigned to the intervention group received personalized physical treatment as described above, as well as deep dry needling (PT +DDN) of the MTrP of the supraspinatus, infraspinatus, subscapularis, teres minor, and deltoid (anterior, medial and posterior) muscles. Needling was performed using the Hong technique ("fast-in, fast-off"), accompanied by the subsequent application of cold spray to diminish the post-needling pain sensation [14,30]. Acupuncture needles measuring  $0.25 \times 0.25$  mm,  $0.30 \times 50$  mm and  $0.30 \times 0.75$  mm with guide tube were used. A total of three needling sessions were carried out, distributed over the first, fourth and seventh sessions respectively, needling the MTRPs once in each session.

Participants were subsequently evaluated by a blinded evaluator at the end of treatment and three months after completion.

## Outcomes and Measurements

The **principal variable** examined was the **perception of pain** as defined by the patient (the cause of their doctor visits), evaluated using the Pain Visual Analogical Scale (PVAS). The visual analogue scale typically consists of a 10-cm horizontal line, with perpendicular lines on the edges, defined as the extreme limits of the pain experience ("no pain" accompanied by the number 0 and "maximum pain ever experienced" accompanied by the number 10). The psychometric usefulness of VAS in pain measurement has been widely demonstrated [31], clinically important improvement on the pain VAS is considered to be 1.5 points [21]

## Secondary efficacy variables were:

**Functionality** was measured with the **Constant-Murley Functional Score** (C-MFS) [32,33] which ranges from 0 to 100 and includes four subscales: for subjective parameters (35%), pain (0 to 15 points) and daily living activities from 0 to 20 points (**ConstantDLA**), for objective parameters, subscale to measure global mobility (0-40 points) collectively integrating all of the movements (flexion, abduction, internal and external rotation) of the shoulder (**ConstantMOV**), and finally the measure of strength from 0 to 25 points (**ConstantSTRENGHT**). Higher scores indicate greater function. This test has presented good reliability and is one of the most frequently used in clinical settings [34,35]

**Number of MTrPs**, active and latent: supraspinatus, infraspinatus, subscapularis (lateral, superior and inferior), teres minor and deltoid (anterior, medial and posterior) muscles were evaluated (the values of variable were 0-9). All of these localizations were based on the nomenclature and localization of Travell and Simons [14]. Diagnosis was made according to the updated Travell and Simons [14,36,18] diagnostic criteria: the presence of a hypersensitive spot in a palpable taut band to identify the PGM (active and latent), and the palpable or visible local twitch response on palpatory stimulus, where possible, to confirm the PGM localization at the time of treatment.

The existence of nocturnal pain was measured also at the end of the treatment and three months later.

**Sociodemographic variables** were also collected (age, gender) as well as clinical evolution variables such as time of evolution.

Patients were assessed at 3 time points: baseline, post-treatment and at the 3-month follow-up. The physical therapists who participated in the study (both those conducting the treatment as well as those evaluating it) had over 5 years prior experience in the physiotherapeutic diagnosis and applied treatment, as well as in the

treatment of the MTRP. However, they also underwent 4 additional sessions of protocol standardization with an expert in this technique. Furthermore, they were provided with a telephone contact to make any necessary consultations regarding doubts or incidents that may arise during the study period.

### Statistical analysis

Clinical efficacy was assessed using intention-to-treat analysis. The worst observation carried forward (WOCF) method was used to handle missing data.

Taking into account the patients diagnosed with SIS and/or RC tendinitis and nocturnal pain, a basal comparison was made between both treatment groups (by means of a t-test), examining key variables to establish the groups' baseline comparability after randomization.

Differences between both groups at the end of the treatment and three months later were analysed using ANCOVA. Thus, for the primary outcome variable and for each pre-specified secondary outcome variable in each time point (post treatment and three months later) we adjusted a linear model in which the type of treatment and the corresponding outcome measure at baseline were the independent variables.

In order to compare the improvement in nocturnal pain (changes from yes to no) between the groups, we applied the Chi-squared test at the end of the treatment and three months later.

In order for the findings from the randomized control trials to have greater meaning for scientists and physical therapists and in accordance with IMMPACT recommendations, [37] we dichotomized participants into those who achieved a relative improvement of 50%, since this is considered to be a "substantial" improvement. Relative improvement of every variable was defined as a quotient between the absolute improvement at post-treatment and the limitation of the scale at baseline. The limitation was considered as the difference between optimal score of the scale/subscale and the score at baseline, except for the PVAS, where the limitation was the baseline value. Therefore, for each variable, participants were classified in a group made up of those who reached a relative improvement of 50% and those who didn't. A comparison between treatments was carried out using a chi-square test.

Finally, the number of scales and subscales (from PVAS scale and CONSTANT sub-scales) that showed a relative improvement of at least 50% was analysed, as well as improvement of nocturnal pain. This overall variable has been compared between treatments with chi-square test and a linear tendency test (Mantel-Haenszel test).

Statistical analyses were performed with the SPSS 22.0 statistical software package.

### Ethical aspects

Informed consent was obtained from participants before they were aware of their group assignment and before any assessment was carried out. Before providing their consent, patients were offered a general overview of the aims and characteristics of the study and interventions, and were informed that they would be participating voluntarily and that they could withdraw at any time with the guarantee that they would continue to receive the treatment considered most appropriate in the Physiotherapy Unit. Data gathering involved no risks for the subjects participating in the study. The study was conducted in

accordance with Helsinki Convention norms. The Study Protocol was approved by the Clinical Research Ethics Committee of Aragon (01/2008).

### Role of the Funding Source

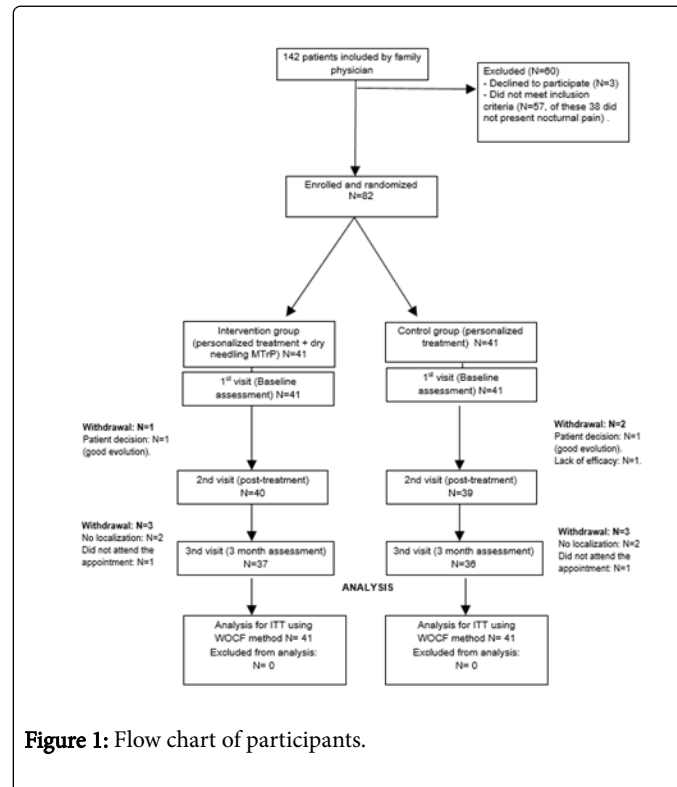
The study was funded by a grant from the Spanish Government's Ministry of Health (PI07/90924). The role of the financing source was to verify that the study was conducted as requested and in compliance with regulations for research and the obtaining of public funding as well as with legislation regarding ethical aspects in the study implementation.

### Results

After applying the inclusion criteria, a total sample of 82 patients with shoulder pain and nocturnal pain was obtained, 41 patients assigned to the control group and 41 to the intervention group.

All patients were analysed using intention-to-treat (ITT) analyses. There were no deviations from the anticipated study protocol [20].

The attrition rate was low. Of the 82 subjects who began the study, 79 completed the treatment, with two losses occurring in the control group (4.87%) and one in the intervention group (2.43%). The 3-month follow-up was completed by 73 subjects, 36 in control group and 37 in intervention group. The final dropout rate was 10.97%. Due to the low dropout rate, predictors of dropout were not subjected to further analysis. Figure 1 illustrates the flow of participants during the trial and the cause of attrition.



**Figure 1:** Flow chart of participants.

Table 1 shows the characteristics of groups, control group and intervention group at baseline assessment. As seen, no significant differences existed between groups.

Clinical variables	PT (n=41)	PT+DDN (n=41)		
	Mean ± S.D.	Mean ± S.D	Mean difference (I.C.95%)	p-value†
PVAS	7.05 ± 1.36	6.63 ± 1.44	-0.41 (-1.03, 0.20)	0.18
Constant-Murley Functional Score	45.46 ± 10.90	48.44 ± 11.94	2.98 (-2.05, 8.00)	0.24
Constant DLA	10.59 ± 4.02	11.51 ± 4.01	0.93 (-0.84, 2.69)	0.3
Constant MOV	29.39 ± 6.91	30.10 ± 6.89	0.71 (-2.32, 3.74)	0.64
Constant STRENGHT	3.90 ± 2.72	4.76 ± 2.88	0.85 (-0.38,2.08)	0.17
Number of MTrP	4.83 ± 1.69	5.15 ± 1.82	0.32 (-0.45, 1.09)	0.42

**Table 1:** Baseline of both groups.

PVAS: Pain Visual Analogical Scale; ConstantDLA: subscale Constant-Murley Score for daily living activity; ConstantMOV: subscale Constant-Murley Score for global range of motion; ConstantSTRENGHT: subscale Constant-Murley Score for evaluation of strength. PT: Personalized Treatment; DDN: Deep Dry Needling. † Independent samples t- test.

Table 2 shows the comparison between both groups at the end of treatment and at the 3-month follow-up, respectively. We can observe that perceived pain improvement shows a mean difference (by means

of ANCOVA) of 1.64 points with the PT+DDN being greater than PT group. This difference is significant. In the variable function (C-MFS), the increase of 12.76 points in the PT+DDN versus 8.02 in the PT group (mean difference in the improvement of 6.8 points by means of ANCOVA) is a significant difference at 5% but not at 1%. However, in the subscale ConstantDLA, we observe twice as much improvement in the PT+DDN with respect to the PT group (4.24 vs. 2.12). Finally, the evolution at three months was equal for both groups. The variable of strength does not show significant improvement for any treatment.

	PT	PT+DDN	Between-group differences**	p-value
<b>PVAS</b>				
Baseline	7.05 ± 1.36	6.63 ± 1.44		
Post-treatment	5.29 ± 2.11	3.61 ± 2.30	1.64 (0.65, 2.62)	0.001
After 3 months	3.78 ± 2.52	3.12 ± 2.60	0.53 (-0.60,1.66)	0.35
Within group improvement from baseline‡				
Post-treatment	1.75 (1.05,2.46)	3.02 (2.14,3.91)		
After 3 months	3.27 (2.53, 4.00)	3.51 (2.55,4.47)		
<b>Constant-Murley Functional Score¶</b>				
Baseline	45.46 ± 10.90	48.44 ± 11.94		
Post-treatment	53.49 ± 13.68	61.20 ± 12.24	6.80 (1.22, 12.37)	0.02
After 3 months	59.54 ± 14.05	62.27 ± 13.24	1.82 (-4.07, 7.70)	0.54
Within group improvement from baseline				
Post-treatment	8.02 (4.03, 12.02)	12.76 (7.49, 18.02)		
After 3 months	14.07 (9.87, 18.28)	13.73 (8.40, 19.26)		
<b>ConstantDLA</b>				
Baseline	10.59 ± 4.02	11.51 ± 4.01		
Post-treatment	12.71 ± 4.63	15.76 ± 4.32	2.84 (0.88, 4.79)	0.005

After 3 months	14.39 ± 4.93	14.88 ± 4.54	0.19 (-1.84, 2.22)	0.85
Within group improvement from baseline <sup>*</sup>				
Post-treatment	2.12 (0.65,3.60)	4.24 (2.35,6.14)		
After 3 months	3.80 (2.20, 5.41)	3.36 (1.62, 5.11)		
<b>ConstantMOV</b>				
Baseline	29.39 ± 6.91	30.10 ± 6.89		
Post-treatment	31.32 ± 7.01	33.44 ± 6.22	1.79 (-0.77, 4.36)	0.17
After 3 months	32.66 ± 6.77	33.80 ± 5.40	0.86 (-1.56, 3.29)	0.48
Within group improvement from baseline <sup>*</sup>				
Post-treatment	1.93 (0.22, 3.64)	3.34 (0.79,5.89)		
After 3 months	3.27 (1.62, 4.91)	3.71 (1.11, 6.30)		
<b>Constant STRENGHT</b>				
Baseline	3.90 ± 2.72	4.76 ± 2.88)		
Post-treatment	4.58 ± 3.06	4.69 ± 2.22)	-0.31 (-1.35, 0.72)	0.55
After 3 months	5.05 ± 2.57)	5.41 ± 2.45)	-0.02 (-0.99, 0.94)	0.96
Within group improvement from baseline <sup>*</sup>				
Post-treatment	0.68 (-0.21,1.58)	-0.07 (-0.90,0.75)		
After 3 months	1.14 (0.31, 1.99)	0.66 (-1.66, 1.48)		
<b>Number of MTrP</b>				
Baseline	4.83 ± 1.69	5.15 ± 1.82)		
Post-treatment	4.12 ± 1.65	4.15 ± 1.93)	0.24 (-0.22,0.70)	0.3
After 3 months	3.85 ± 1.89	4.15 ± 1.94)	-0.03 (-0.59, 0.53)	0.91
Within group improvement from baseline <sup>*</sup>				
Post-treatment	0.71 (0.43, 0.98)	1.00 (0.61,1.39)		
After 3 months	0.97 (0.26, 1.32)	1.00 (0.54, 1.46)		

**Table 2:** Comparison of pain and function and its subscales improvement between treatments at post-treatment and 3-month assessment.

PVAS: Pain Visual Analogical Scale; ConstantDLA: subscale Constant-Murley Score for daily living activity; ConstantMOV: subscale Constant-Murley Score for global range of motion; ConstantSTRENGHT: subscale Constant-Murley Score for evaluation of strength. PT: Personalized Treatment; DDN: Deep Dry Needling. Values are mean ± S.D. unless otherwise indicated. \*\*Values are mean difference (95% confidence interval) between both treatments by using analysis of covariance (outcome score at different time points is the dependent variable and the corresponding variable at baseline is the covariable). \*Values are mean difference (95% confidence interval).

Improvement calculated as the increment of the variable. ‡Values are mean difference (95% confidence interval). Improvement calculated as the reduction of the variable.

Of the 41 subjects that were randomly selected for PT, 16 of these (39%) did not present nocturnal pain at the end of the treatment. At three months, 20 subjects no longer presented nocturnal pain (48.7%). Regarding the PT+DDN group, of the 41 subjects who began it, 25 patients (60.9%) no longer had night pain in the post-treatment and 21 (51.2%) no longer had night pain at the 3-month follow-up (Table 3).

	Post-treatment Improvement	3-months Improvement
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	No (41)	Yes (41)	No (41)	Yes (41)
Nocturnal Pain				
PT (41)	25	16	21	20
PT+DDN (41)	16	25	20	21
Odds ratio (Yes /No) (I.C. 95%)	0.41 (0.17, 0.99)		0.91 (0.38, 2.15)	
p-value	0.04		0.82	
PT: Personalized Treatment; DDN: Deep Dry Needling. § Chi Squared test				

**Table 3:** Comparison of Nocturnal Pain improvement between treatments at post-treatment and 3-month assessment.

Improvement ±	PT (41)	PT+DDN (41)	p-values
PVAS pain improvement >=50% (No/Yes)	32/9	21/20	0.01
ConstantDLA improvement >=50 (No/Yes)	28/13	18/23	0.026
ConstantMOV improvement >=50% (No/Yes)	26/15	21/20	0.26
ConstantSTRENGTH improvement >=50 (No/Yes)	41/0	41/0	1
Nocturnal Pain improvement (No/Yes)	25/16	16/25	0.048
PT: Personalized Treatment; DDN: Deep Dry Needling; PVAS: Pain Visual Analogical Scale; ConstantDLA: Subscale Constant-Murley Score for daily living activity; ConstantMOV: Subscale Constant-Murley Score for global range of motion; ConstantSTRENGTH: Subscale Constant-Murley Score for evaluation of strength. § Chi Squared test			

**Table 4:** Comparison of both groups of treatment, in perceived pain, function variables and nocturnal pain, assuming 50% improvement at post-treatment.

Number of variables with improvement of 50% or plus	PT	PT+DDN
	n (%)	n (%)
0 variables improve	13 (31.7%)	9 (22%)
1 variable improves	10 (24.4%)	7 (17.1%)
2 variables improve	12 (29.3%)	6 (14.6%)
3 variables improve	5 (12.2%)	7 (17.1%)
4 variables improve	1 (2.4%)	12 (29.3%)
Chi-squared Test (p-value)	12.90 (0.01)	
Linear trend Test (p-value)	7.44 (0.006)	
PT: Personalized Treatment; DDN: Deep Dry Needling. The variables considered are PVAS and CFS subscales adding the improvement of night pain.		

**Table 5:** Comparison of the number of patient with 50% improvement in k variables, between both groups at post-treatment.

To deepen the post-treatment analysis, we attempted to identify the magnitude of those improvements; Table 4 shows the subjects who

improved by 50% in the main variables: perception of pain, function (subscales of C-MFS) and existence or not of night pain, just at post-treatment, without significant improvement in either range of motion or strength. And Table 5 shows the number of those variables in which a patient improved by 50% (together with the improvement of nocturnal pain), and we can see the different trend of the number of variables that improve by 50% in each subject according to the treatment administered. The variable strength as previous results (ConstantSTRENGTH in Table 2) was not included since any subject's revealed improvement of 50%.

## Discussion

A significant difference in the decrease of pain was observed after intervention, as was the tendency to obtain a significant improvement in a higher number of variables in patients treated with DDN, in MTrPs, when compared to patients in the control group which did not receive DDN. These patients revealed better improvement in pain (PVAS) and in daily living activities (ConstantDLA) at post treatment but not at the 3-month follow-up. Furthermore, these patients had a better response to DDN treatment in terms of relative improvement, with a higher number of patients obtaining at least 50% of improvement in 3 or 4 of the analysed outcome variables. DDN could be helping the overall improvement in these patients, benefitting in more short-term variables.

It is necessary to note that these significant differences in the improvement between patients with shoulder nocturnal pain occur in the PVAS and ConstantDLA (with a 5% significant change measured in global function). We should mention that these differences occur in subjective variables [34] (pain and the daily activities) but not in objective measurements such as range of motion or strength. This may be in line with Tekeoglu who previously found an inverse relationship between sleep quality and severity of pain and dysfunction in subacromial pathology [38,39] and considers that a poorer sleep quality may worsen pain perception and reduce the ability to manage pain, developing a vicious circle. Similar findings were found by Gerber in a study carried out with students and workers at George Mason University (USA) on people having active and latent MTrPs. Those who had active MTrPs had different physical findings, perceived pain, sleep impairment disability, own health perception and state of mind when compared to people having latent MTrPs [40]. 79.2% of those with myofascial pain syndrome presented sleep impairments related to their musculoskeletal pain.

Musculoskeletal sensitization combined with sleep fragmentation may model aspects of the relationship between sleep and pain reported

in humans. This synergistic association exerts an exacerbation of mechanical hypersensitivity [6]. After treatment, we can consider this relationship in an inverse sense, thereby breaking an element of this circuit-- the musculoskeletal sensitization-- by means of the dry needling of active MTrP, [18] contributing to further improvement in those patients with nocturnal pain. It is also possible that the effect of merely inserting a needle into the skin and subcutaneous tissues stimulates A-delta nerve fibres with the consequent release of opioid peptides from enkephalinergic inhibitory interneurons in the dorsal horn, [41] and it is also possible that the superficial dry needling can activate the mechanoreceptors coupled to the unmyelinated afferent C fibres of slow conduction [42]. Such activation could lead to a decrease in pain and a feeling of improvement and well-being through the activation of the insular region and the anterior cingulate cortex [43]. Furthermore, the hyperalgesia effect of partial sleep deprivation is mediated by impairments in the descending pain modulatory systems, rather than an amplification of the ascending sensory pathways. This has been seen in the significant attenuated electroencephalographic activity insular and cingulate regions activity after partial sleep deprivation and reduced conditioned pain modulation [5].

The number of studies focusing on nocturnal shoulder pain is sparse, even more so when considering intervention protocols [39]. According to the results obtained in current study and as Mulligan has stated, identifying patients with shoulder pain as well as poor sleep quality may be an important first step in establishing a therapeutic plan, [38] and furthermore, it may be useful to identify possible muscle pain in patients with a poor sleep quality. DDN may become in an elective technique for treating patients presenting shoulder pain when they manifest with nocturnal pain. This is due to the fact that improvement occurs in a shorter and more limited period of time. However, at the 3-month follow-up, there are no significant differences between groups.

When examining the predicting factors of shoulder disorders, few studies have considered nocturnal pain as no favourable predictive factor to response of physiotherapy treatment [44,45]. Cadogan is anticipated giving the importance to night pain, and although no significant, she found it as no favourable factor to a positive response to injection of local anaesthetic into the subacromial bursa, and the presence of night pain were found to be strong predictors of a rotator cuff tear [2,46].

As our results, nocturnal pain can have a not small influence in outcomes of physical therapy, and could be one of the variables to be considered, and may serve as a clinical element when determining the most suitable physiotherapy treatment method for each patient. Deep dry needling is suggested as a therapeutic approach for this type of patient.

This study is innovative as it considers the nocturnal pain shoulder phenomenon in patients with musculoskeletal pain in Primary Health Care, with an adequate sample size and representativeness. Furthermore, it included a 3-month follow up period, enabling the analysis of patient evolution once the treatment was completed. On the other hand, this study also has some limitations: one of these is that the diagnosis was made according to clinical symptoms and examination, although it was confirmed by US or MRI for 91% of the patients. In addition, we did not use any specific questionnaire for sleep quality (e.g. PSQI) or analyse any other components of the quality of night rest.

## Conclusions

Shoulder pain is a very prevalent problem with a large percentage of this population also presenting nocturnal pain. DDN of MTrPs may be considered an elective technique for this population, given that significant improvements were achieved over the short term as compared to patients not receiving DDN. However, a personalized treatment based on an initial assessment and using different physiotherapy techniques may achieve the same results, although over a longer period of time.

## Acknowledgement

The study was funded by a grant from the Spanish Government's Ministry of Health (PI07/90924). The role of the financing source was to verify that the study was conducted as requested and in compliance with regulations for research and the obtaining of public funding as well as with legislation regarding ethical aspects in the study implementation.

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