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Single-point acupuncture and physiotherapy for the treatment of painful shoulder: a multicentre randomized controlled trial

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Objective. Evaluate the efficacy of acupuncture associated with physiotherapy for patients with painful shoulder.
Methods. In a multicentre controlled randomized study, participants were recruited with a clinical diagnosis of unilateral subacromial syndrome from six rehabilitation medicine departments belonging to the Public Health System in two Spanish regions. All participants received 15 sessions of physiotherapy during the 3 weeks that the treatment lasted and were randomized to additionally receive, once a week, acupuncture or mock TENS (transcutaneous electrical nerve stimulation). The primary outcome measure was the change in the Constant–Murley Score (CMS) for functional assessment of the shoulder, at 4 weeks after randomization. This study is registered as an International Standard Randomized Controlled Trial, number ISRCTN28687220.
Results. A total of 425 patients were recruited. The mean score (S.D.) on the CMS had increased by 16.6 (15.6) points among the acupuncture group, compared with 10.6 (13.5) points in the control group, and the mean difference between the two groups was statistically significant (6.0 points; 95% CI 3.2, 8.8 points; $P < 0.001$). By the end of the treatment, 53% of the patients in the acupuncture group had decreased their consumption of analgesics, compared with a corresponding 30% among the control group ($P < 0.001$).
Conclusions. Single-point acupuncture in association with physiotherapy improves shoulder function and alleviates pain, compared with physiotherapy as the sole treatment. This improvement is accompanied by a reduction in the consumption of analgesic medicaments.

Key words: Shoulder pain, Acupuncture, Randomized clinical trial, Physiotherapy, Pain treatment, Single-point acupuncture, Subacromial syndrome, Rotator cuff tendinitis, Subacromial bursitis, Mock transcutaneous electrical nerve stimulation.

Introduction

Painful shoulder is one of the most common disorders affecting the locomotor apparatus, and is frequently encountered both in primary healthcare clinics and by specialists, with an annual incidence in the former case of 1.2% [1, 2]. One of the most common causes of painful shoulder is subacromial syndrome, including rotator cuff and biceps tendinosis, calcifying tendinitis, subacromial bursitis and rotator cuff rupture; this pathology, which becomes more common with increased age [3] and with the practice of certain occupational and sporting activities [4], is mainly evidenced by pain, limited movement and strength, and the loss of shoulder function. The incidence on occupational incapacity, reported by most authors, remains unknown, as only approximate data are available, such as those supplied by Instituto de Biomecánica de Valencia, which estimates that 50% of work time lost for sick leave is due to muscle or bone injury in the cervical–scapular area (rate of incidence of musculo-skeletal lesions: 5.4 days' sick leave per 100 workers).

The most common methods currently applied to alleviate the symptoms of painful shoulder include the injection of steroids, physiotherapy, oral NSAIDs and 'wait and see', but very few of these are corroborated by scientific study [5]. There is very little evidence on the effectiveness of physiotherapy in subacromial syndrome, due to the scarcity of sample data and the lack of methodological rigour in the studies published [1], while one of the main problems observed in this respect has been the lack of consensus concerning the treatment regime to be applied [6]. It has been shown that exercise is effective as regards the short-term recovery from rotator cuff lesions, and that it is beneficial in the longer term with respect to function. Moreover, the combination of mobilization and exercise provides additional beneficial effects, in comparison with exercise as the sole treatment. The evidence as concerns ultrasound therapy has shown the latter to be not effective in the treatment of painful shoulder [1, 7, 8].

According to recent studies, acupuncture might be a viable therapeutic option for painful shoulder [9–12], but to date little evidence has been produced to corroborate its use in the treatment of this pathology, and calls have been made for further well-designed clinical trials to be carried out [4]. In the present study, we propose the hypothesis that single-point acupuncture (stomach 38), associated with a specific programme of physiotherapy might be capable of reducing pain and improving function in cases of subacromial syndrome (rotator cuff tendinitis and subacromial bursitis) to a greater extent than physiotherapy associated with non-activated transcutaneous electrical nerve stimulation (mock TENS).

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Materials and methods

Design

The protocol of this study has been published previously [13]. It consists of a randomized controlled multicentre study with blind observation by an independent observer and blind, independent analysis. The patients were randomly allocated to one of the two study groups: (i) an experimental group, treated with acupuncture, in association with physiotherapy; (ii) a control group, treated with mock TENS and physiotherapy. Each clinic that participated in the study was equipped with a digital data acquisition unit (DDAU). The randomization sequence was performed in a centralized way and recorded in encrypted form in each DDAU, such that when the data for a new patient were introduced, a treatment code related to the patient's ID number was assigned (this code was concealed from the evaluator). The study team took the necessary precautions to maintain the confidentiality of the information on the patients taking part, including the de-identification of the databases constructed for subsequent analysis. All patients were informed about the preconditions and procedures of the study, and provided oral and written consent. The study was approved by the Andalusian Clinical Trials Committee (CAEC) and by six local ethics committees.

Patients

The patients included had been referred to the six Rehabilitation Medicine Departments belonging to the Public Health System in two Spanish regions (Andalusia and Murcia). These patients presented chronic symptoms of unilateral subacromial syndrome (rotator cuff tendinitis or subacromial bursitis, in some cases associated with capsulitis), with a case history duration equal to or exceeding 3 months and with normal shoulder radiography results. These patients were offered either physiotherapy associated with acupuncture, or alternatively, physiotherapy associated with TENS, and were informed that one of the techniques could be false (placebo). They were explained the study design and the techniques that would be applied, as well as the possible risks (infection, fainting, bruising). They were also informed that their participation in the study could be terminated at any time, with no kind of penalty or loss of benefits. The following main criteria for exclusion were applied: prior surgery, dislocations or fractures in the area of the shoulder clearly related to the onset of the current pain experienced, pregnancy, anticoagulant treatment, generalized disorders of the musculo-skeletal system, neurological disorders, vascular trophic disorders in the lower limbs or the presence of lymphoedema.

Description of the interventions

The following actions, which are described in detail elsewhere [13], were taken.

Acupuncture. Three acupuncture sessions were applied, once a week, by the doctor responsible for the treatment (one doctor at each participating clinic, trained in this technique, with an average experience of 7.5 yrs). The puncture was made at a single acupuncture point (Tiaokou, stomach 38, homolateral), in accordance with the *tiao–shan* technique (this consists of the perpendicular insertion of a single-use sterile filiform acupuncture needle, 7.5 cm long, 30-gauge body diameter, using a guide-tube; the insertion is to be made, after sterilizing the skin and with the patient in a supine position, at the Tiaokou point [located equidistally from the flexion fold of the knee and the vertex of the lateral malleolus and 1 inch laterally from the tibial crest], to a depth of 4.5–5.0 cm, towards the Chengshan BL57 point, located at the centre of the calf, followed by stimulation with rotation movements of the needle through an arc of at least 180° in order to achieve the sensation known as *Deqi* (sensation of numbness, tingling and/or local tension) and a sensation irradiating throughout the lower limb. The needle was kept in place for 20 min, and manipulated for 1 min every 5 min (with a total of four manipulations per session). During the periods of manipulation, the patient performed active mobilization of the shoulder, in abduction and internal and external rotation.

Mock TENS. Once a week for 3 weeks the doctors responsible for the treatment applied two adhesive electrodes to the front and back of the leg on the same side of the body as the affected shoulder; these electrodes were connected to an inactivated TENS apparatus. The stimulation unit remained in front of the patient so that he/she could observe the flashing diode that simulated the stimulus, for the 20 min of the session. The TENS potentiometer was monitored every 5 min. After the session, the TENS unit was disconnected and the electrodes were removed from the patient's body.

Physiotherapy. All the patients received 15 sessions of physiotherapy during the 3 weeks that the treatment lasted. These sessions were applied by trained physiotherapists (with an average experience of 17.25 yrs), for a duration of 40 min. The physiotherapy treatment began the day after the mock TENS or acupuncture session. They consisted of the following activities: superficial thermotherapy (graduated according to the patient's level of perceived comfort, duration 5 min); recentring of the humeral head with active manoeuvres (5 min) and passive manoeuvres (5 min); dynamic control of the scapula (5 min); cryotherapy (10 min); accompanied by a series of recommendations aimed at maintaining the results obtained (10 min).

The acupuncture and the mock-TENS sessions were applied within identical rooms and prior to the physiotherapy. Throughout the study period the patients were allowed to take analgesic and/or NSAID medication, on request, and the daily quantity thus consumed, together with the recommended daily dose, was recorded in the DDAU.

Baseline assessment and outcome measures

The baseline variables included sociodemographic and occupational data, information on the severity of the process and relevant previous episodes, numerical evaluation scales of pain intensity, both by day and by night, the total duration of the pain and potentially prognostic variables. The result measures were obtained after 4 weeks and at 3, 6 and 12 months after randomization. Shoulder function was assessed using the Constant–Murley Score (CMS) [14, 15]. The CMS combines 35% subjective parameters (pain 15%, tasks of daily living 20%) and 65% objective parameters (range of motion 40%, strength 25%) with a maximum of 100 points, indicating a shoulder with mobility completely free from pain and with normal functioning. The baseline evaluations at 4 weeks and at 3 months were supervised by rehabilitation evaluators who were blinded to the type of treatment applied to each subject; these personnel (with an average experience of 9.2 yrs) had been trained in the evaluation techniques employed in the study, and belonged to the same rehabilitation service where the techniques were provided; at no time did the evaluators intervene in the treatment of the patients included in the study. The data in the evaluation questionnaires completed at 6 and 12 months were obtained by telephone interviewers who were also unaware of the type of treatment applied to each subject. In addition, the patients filled in a questionnaire on their confidence in the treatment [16, 17] at the end of the first week of treatment. An evaluation was also obtained of the degree of improvement perceived by the patient and the degree of improvement perceived by the evaluator [18]. In the follow-up at 6 and 12 months, data were obtained on the appearance of new episodes of pain, their duration and the treatment received. Significant adverse events observed were recorded, as were those reported by patients, doctors and physiotherapists.

As specified in the study protocol [13], the primary outcome measure was the change in the CMS from the baseline value after

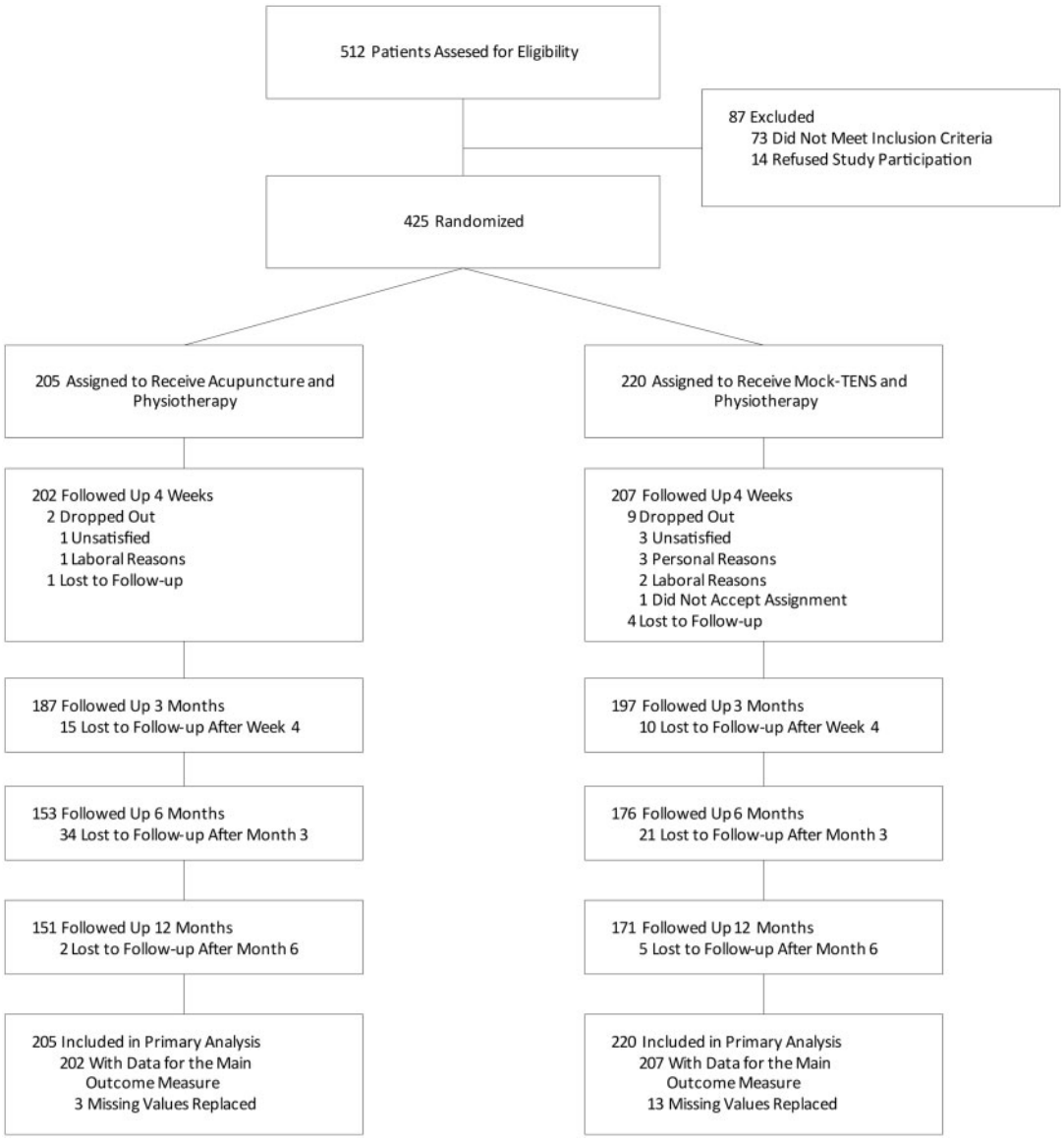

FIG. 1. Study design.

4 weeks. Secondary measures included change in the CMS at 3, 6 and 12 months after randomization (in the follow-up evaluation at 6 and 12 months, only the subjective CMS parameters were recorded), patients' self-reported improvement, the improvement perceived by the evaluator, the daytime and night-time intensity of shoulder pain as registered on the 11-point numerical rating scale (NRS), the number of new episodes of pain and their duration, the number and duration of days' sick leave, the consumption of analgesic drugs and/or NSAIDs and other types of co-interventions.

Data analysis

The sample size was based on historic data [9, 10] (with a two-sided significance level of 0.05 and 80% power) to detect a between-group difference of 15 points on the CMS. Assuming a dropout rate of 20%, the total sample size was 465 patients. No interim analysis was proposed. The sociodemographic and clinical variables were summarized by treatment group, for all the randomized patients. The treatment groups were compared by using the two-sample *t*-test (numerical data) and the χ^2 test (categoric data). The statistical analysis was performed by persons who were unaware of the allocation to treatment groups. All the hypothesis tests were two tailed with $\alpha = 0.05$.

The confirmatory analysis of the principal result measure was carried out on the intention to treat (ITT) population, replacing the missing values with the mean ones obtained for each group. For the primary outcome variable, we calculated the difference between the final and the baseline CMS values, compared the two groups and performed a multivariate analysis by linear regression, adjusting for the baseline value and forcing the inclusion of the treatment group variable and other possible confounding variables. The forward-wise model was used to select the possible confounding variables in the model, and the entry criterion applied was the level of statistical significance. In addition, we compared the groups with the variables recorded in the 3-, 6- and 12-month assessments. All the analyses were carried out using SPSS software version 14.0 (SPSS Inc, Chicago, IL, USA).

Results

The study was carried out from January 2005 to December 2006. Of the 512 patients who were considered for selection, 425 presenting subacromial syndrome were recruited (307 women and 118 men), at six rehabilitation medicine departments (Fig. 1).

TABLE 1. Patients' baseline demographic characteristics and clinical findings[a]

	All patients ($n=425$)	Acupuncture and physiotherapy ($n=205$)	Mock-TENS and physiotherapy ($n=220$)
Women	307 (72)	152 (74)	155 (70)
Age (S.D.) (yrs)	55.7 (11.4)	54.9 (10.8)	56.4 (11.8)
Painful shoulder (subacromial syndrome)			
Rotator cuff tendinitis	325 (77)	160 (78)	165 (75)
Subacromial bursitis	52 (12)	24 (12)	28 (13)
Adhesive capsulitis[b]	48 (11)	21 (10)	27 (12)
Associated neck pain	265 (62)	130 (63)	135 (61)
Dominant shoulder	255 (60)	132 (64)	123 (56)
Duration of the present episode, mean (S.D.) (months)	8.4 (4.5)	8.5 (4.7)	8.4 (4.4)
Daytime pain, mean (S.D.) (NRS)[c]	5.2 (1.8)	5.3 (1.9)	5.2 (1.7)
Night-time pain, mean (S.D.) (NRS)[c]	6.3 (2.6)	6.4 (2.3)	6.3 (2.7)
Pain and disability, mean (S.D.) (CMS)[d]			
Overall score	43.0 (13.4)	44.1 (13.8)	42.0 (13.0)
Subjective parameters	12.5 (5.3)	13.0 (5.6)	12.0 (5.0)
Objective parameters	30.5 (10.5)	31.1 (11.0)	30.0 (10.0)
Credibility test, mean (S.D.)[e]			
(i) Are you confident this treatment will alleviate the pain you feel?	7.8 (1.9)	7.8 (1.9)	7.7 (1.9)
(ii) Does the treatment seem a logical one?	7.5 (2.1)	7.5 (2.1)	7.5 (2.1)
(iii) Would you recommend this treatment to a friend or relative who had the same problem?	7.4 (2.2)	7.6 (2.1)	7.3 (2.3)
(iv) Do you think this treatment could be applied to other problems?	7.3 (2.3)	7.4 (2.1)	7.2 (2.4)
Previous treatment			
Analgesics	350 (82)	167 (82)	183 (83)
NSAIDs	315 (74)	151 (74)	164 (75)
Local injections	111 (26)	51 (25)	60 (27)

[a]Data are no. (%) unless otherwise specified. All between-group differences non-significant at the ≥ 0.05 level. [b]Associated with one or more of the above conditions. [c]Rating scale 0–10, higher score indicates more severe pain. [d]Overall score 0–100, higher score indicates less severe symptoms (subjective score 0–35; objective score 0–65). [e]Items assessed (after the first session of acupuncture or mock TENS) on a continuous visual analogue scale 0–10, with 0 being totally disagree and 10 being totally agree.

The study population had a mean age (S.D.) of 55.7 (11.4) yrs, and were mostly female, diagnosed with rotator cuff tendinitis of the dominant shoulder, accompanied by neck pain and had previously received pharmacological treatment with analgesics and NSAIDs. The mean duration of the pain was 8.4 (S.D. 4.5) months. All the baseline characteristics were comparable between the two groups (Table 1). Sixteen patients failed to complete the treatment programme or were lost to follow-up, 3 of them (0.7%) in the acupuncture group and 13 (3%) in the mock TENS group ($P=0.02$, χ^2 test), and the characteristics of these patients who did not complete the treatment were very similar to those of the rest of the participants.

The credibility tests carried out on the two groups did not produce any results that might have led us to doubt the techniques.

One week after finalizing the 3 week treatment programme, and according to ITT analysis, the average CMS score in the experimental group was 60.6 (S.D. 17.6) points, which represented a mean increase of 16.6 (S.D. 15.6) points over the baseline score; the mean final score of the control group was 52.5 (S.D. 13.1) points, with a mean increase of 10.6 (S.D. 13.5) points: the mean difference between the two groups for the increase in the CMS score was 6.0 points (95% CI 3.2, 8.8; $P<0.001$), and a medium effect size of 0.4 was achieved [19]. After adjusting for the baseline differences, the mean CMS increase was 6.9 points greater in the acupuncture group than in the control group (95% CI 4.3, 9.5). In the final multivariate model, for the CMS result variable, adjusted for its baseline level and for baseline daytime pain, previous consumption of anti-inflammatory medication and days' sick leave, the average difference was 7.2 points (95% CI 9.6, 4.7) between the experimental and the control group. Diagnosis of the model did not reveal influential points (the maximum Cook's distance was 0.047) and both the normal P-P curve of the standardized residues and that of the studentized residues presented normal distributions and constant variances.

Daytime pain, by ITT analysis, was reduced by 2.0 (S.D. 2.3) points, with respect to the baseline evaluation, in the experimental group, in comparison with the 1.1 (S.D. 2.3) point reduction in the control group, with a mean difference of -0.9 points (95% CI -1.3, -0.4; $P<0.001$). The intensity of night-time pain followed the same pattern, with a reduction from the baseline evaluation of 3.1 (S.D. 2.7) points in the experimental group and a reduction of 2.1 (S.D. 3.4) points in the control group, with a mean difference of -0.9 points (95% CI -1.5, -0.3; $P<0.001$).

At 1 month after randomization, and according to ITT analysis, 53.2% of the patients (109/205) in the experimental group reported a reduction in the consumption of analgesic and NSAID medication, with respect to the baseline level, in comparison with 30% (66/220) of the control group ($P<0.001$).

The per protocol follow-up at 3 months revealed an increase in the overall CMS differences; with respect to the baseline levels, the corresponding figures were 25.4 (S.D. 15.5) points in the experimental group and 14.7 (S.D. 18.0) points in the control group. The mean difference, thus, was 10.7 points (95% CI 7.3, 14.1; $P<0.001$) with a medium effect size of 0.64. The subjective CMS parameters recorded during the follow-up period presented a constant increase in the difference between the two groups, up to 12 months, which was also found for daytime and night-time pain intensity. The intermediate and endpoint measurements obtained are shown in Tables 2 and 3.

The patients self-evaluated the improvement achieved at 1 month after beginning treatment, and the mean difference reported was 0.8 points (95% CI 0.4, 1.2; $P<0.001$). The analysis made with the variable 'improvement perceived by the evaluator' followed the same pattern, with a mean difference of 0.8 points (95% CI 0.5, 1.2; $P<0.001$). The correlation between the patients' perceived improvement and that perceived by the evaluators was 0.82. The mean difference between the groups with respect to new episodes of days' sick leave was 0.025 (95% CI 0.003, 0.048; $P=0.025$). There was no difference between the groups with respect to the number of new episodes in the evaluations at 3, 6 and 12 months.

Adverse events

No significant adverse event was reported in either of the two groups. The great majority of patients (92% in the acupuncture group and 98% in the control group) reported no adverse event concerning the treatment technique employed; 4 (2%) of the patients who received acupuncture treatment referred to intense pain at the moment the technique was applied, and residual pain exceeding 24 h. The most commonly mentioned adverse event

TABLE 2. Primary and secondary continuous outcomes[a] per ITT and per protocol analysis

	1 Month (ITT)			3 Months (PP)			6 Months (PP)			12 Months (PP)		
	Acupuncture ($n=205$)	Mock TENS ($n=220$)	Mean difference (95% CI)	Acupuncture ($n=187$)	Mock TENS ($n=197$)	Mean difference (95% CI)	Acupuncture ($n=153$)	Mock TENS ($n=176$)	Mean difference (95% CI)	Acupuncture ($n=151$)	Mock TENS ($n=171$)	Mean difference (95% CI)
CMS												
Overall score	60.6 (17.6)	52.5 (13.1)	8.1 (5.1, 11.1)	70.1 (14.9)	57.1 (16.6)	12.9 (9.7, 16.1)	NA	NA	NA	NA	NA	NA
Subjective parameters	22.0 (8.6)	18.1 (6.5)	4.0 (2.5, 5.4)	26.6, (8.5)	20.6, (8.8)	6.0 (4.2, 7.7)	29.1, (7.0)	20.9, (9.4)	8.2, (6.4, 10.0)	30.6 (6.9)	22.7 (9.1)	7.9 (6.2, 9.7)
Objective parameters	38.6 (11.0)	34.4 (9.7)	4.1 (2.2 to 6.1)	43.5 (8.9)	36.5 (10.0)	6.9 (5.0, 8.8)	NA	NA	NA	NA	NA	NA
Daytime pain (NRS)	3.2 (2.2)	4.4 (1.9)	−1.2 (−1.6, −0.8)	2.1 (2.5)	3.7 (2.6)	−1.6 (−2.0, −1.0)	2.3 (2.9)	4.6 (3.3)	−2.3 (−3.0, −1.6)	1.6 (2.6)	3.8 (3.1)	−2.2 (−2.8, −1.6)
Night-time pain (NRS)	3.5 (2.3)	5.1 (2.8)	−1.6 (−2.1, −1.0)	2.6 (3.0)	4.2 (3.1)	−1.7 (−2.3, −1.1)	1.8 (2.7)	4.5 (3.5)	−2.7 (−3.4, −2.0)	1.2 (2.3)	3.9 (3.3)	−2.7 (−3.3, −2.0)

[a]Data are means (S.D.).
PP, per-protocol; NA, not applicable.

related to the pharmacological treatment was gastralgia (3% in the acupuncture group and 5% in the control group). Four patients in the experimental group and two in the control group reported an increase in pain after the physiotherapy sessions.

Discussion

Principal findings

The results obtained of this study, the largest one to be carried out on acupuncture treatment for painful shoulder, show that single-point acupuncture, associated with a programme of physiotherapy, is more effective than when physiotherapy is associated with mock TENS. The greater improvement obtained in the group treated with acupuncture, as regards both overall CMS and each of its subscales, by the end of the treatment programme was statistically significant, and this difference not only persisted but also continued to increase during the 3 months after the treatment ended. On the subjective CMS scale, significant differences continued to increase until the 6-month follow-up and remained at similar levels at 12 months. The perceived changes in daytime and night-time pain intensity followed the same pattern as the CMS results.

Similar effects were observed for the secondary variables: consumption of analgesics and NSAIDs, the need for pharmacological treatment and patients' perception of improvement—an outcome of 'much better' was reported by 75% of the patients in the experimental group at 1 yr after completing the treatment. Also noteworthy is the safety of the technique, with no significant adverse effects being observed.

Methodological limitations

Although this study shows the single-point acupuncture technique to be effective, it is probable that a selection combining the use of distal and local acupuncture points would have improved results still further, and widened the differences between the two groups. We chose to apply a simple method (that of acupuncture at a single point) taking into account previous results, which had shown that immediate pain relief and improved function in the painful shoulder could thus be achieved [20]. On this basis, we believed that, once analgesia had been achieved by means of acupuncture, the association of physiotherapy to improve the recovery of the affected shoulder might well improve upon the final results obtained by physiotherapy as the sole treatment. This technique has been shown to be effective in various studies [21–23].

Although the impossibility of using double-blinding in studies of acupuncture might constitute a limitation, the rigorous blinding that was applied in the other phases of the study, both in its evaluation and in the analysis of the final data, as well as in the credibility tests completed by the study population, leads us to believe that this limitation has been controlled as far as possible. A multicentre study of this nature, given the characteristics of the techniques utilized in it, physiotherapy and acupuncture, involves the intervention of diverse healthcare professionals, working in different places. Therefore, there might be variations influencing the results achieved; this was counteracted by subjecting the method to a strict protocol, both as regards the technique (a specific programme of physiotherapy and single-point acupuncture) and the experience of all the healthcare professionals who participated in the study. With these premises, the healthcare clinic in which the study was carried out was not included in the multivariate model as a confounding variable.

Another possible limitation could arise from the fact that mock TENS might not be credible in the context of the information provided to the patients, as they might have evaluated the credibility of the procedure by scoring the physiotherapy

TABLE 3. Secondary categoric outcomes (per protocol analyses)[a]

	1 Month			3 Months		
	Acupuncture ($n=202$)	Mock TENS ($n=207$)	*P*-value[b]	Acupuncture ($n=187$)	Mock TENS ($n=197$)	*P*-value[b]
Consumption of analgesics and antiinflammatory drugs						
No	129 (64)	47 (23)	<0.001	140 (75)	62 (32)	<0.001
Dose below that prescribed	37 (18)	41 (20)		30 (16)	55 (28)	
Prescribed dose	29 (14)	113 (55)		11 (6)	59 (30)	
Dose above that prescribed	2 (1)	4 (2)		0 (0)	10 (5)	
Extra drugs	5 (3)	2 (1)		6 (3)	11 (6)	
	6 Months			12 Months		
	Acupuncture ($n=153$)	Mock TENS ($n=176$)	*P*-value[c]	Acupuncture ($n=151$)	Mock TENS ($n=171$)	*P*-value[c]
Persistence of the pain	74 (35)	138 (65)	<0.001	52 (34)	122 (71)	<0.001
New episode of painful shoulder	19 (12)	19 (11)	0.386	16 (11)	12 (7)	0.174
Other co-interventions						
Pharmacological	32 (16)	86 (40)	<0.001	18 (9)	58 (26)	<0.001
Intra-articular injections	16 (8)	19 (9)	0.447	4 (2)	22 (10)	<0.001
Physiotherapy	0 (0)	10 (5)	0.001	0 (0)	6 (3)	0.019
Acupuncture				0 (0)	5 (2)	0.036
Surgery	4 (2)	0 (0)	0.053	0 (0)	2 (1)	0.267
Self evaluation						
Worse	2 (1)	4 (2)	<0.001[b]	0 (0)	6 (4)	<0.001[b]
Slightly worse	2 (1)	4 (2)		0 (0)	5 (3)	
Unchanged	11 (7)	58 (33)		18 (12)	59 (35)	
Slightly improved	15 (10)	18 (10)		3 (2)	21 (12)	
Improved	22 (14)	37 (21)		17 (11)	24 (14)	
Greatly improved	101 (66)	55 (31)		113 (75)	56 (33)	

[a]Data are expressed as no. (%). [b]Pearson χ^2-test. [c]Fisher's exact test.

rather than the acupuncture or the mock TENS, thus producing a differential classification bias. It would be advisable to be very careful in wording credibility questionnaires when associated interventions are involved. It is not known whether the psychological impact of mock TENS is similar to that of true acupuncture.

The primary outcome considered, the CMS scale, is considered a good instrument for the functional evaluation of the shoulder, and has been validated for use in our context. Nevertheless, studies published in recent years [24, 25] have highlighted its limitations in clinical practice when used in heterogeneous population groups; in such circumstances, the normalized scale should be used. In the present study, although the normalized scale has not been validated for use in Spain, and thus was not used, the study population is sufficiently homogeneous, in our opinion, for the results not to be skewed by the choice of measurement instrument.

Comparison with other studies

Although comparison with other studies is complicated by the complexity of the pathology of painful shoulder, in which there may be various types of lesions, with diverse prognoses, and different varieties of acupuncture and placebo, results have been reported that are in the same line as those we have obtained, although with some variations.

Guerra de Hoyos *et al.* [26] carried out a study of a population similar to ours as regards sociodemographic characteristics and the predominance of tendinitis over capsulitis; the reduction in pain intensity they report, measured on a visual analogue scale at 3 and 6 months, was in the same line as our results. In our case, this trend was maintained at the 12-month follow-up, for both daytime and night-time pain intensity. The between-group differences were similar in the two studies, although the CIs were somewhat narrower, as the sample in our study was larger. Comparison with our technique, employing a single acupuncture point and a lower number of sessions, corroborates the efficacy of acupuncture for this type of lesion.

Although Sun *et al.* [10] used the CMS as the primary outcome variable, and the single distal point acupuncture technique, the patients included presented only adhesive capsulitis. Nevertheless, the improvements observed were in the same line as the ones reported in the present study.

The changes in CMS reported in the study by Kleinhenz *et al.* [9] are also in the same line as the results we report, although their study population presents some differences that make comparison complicated. Their study was based on sports players, who had a better baseline CMS than that of our population, and used a combination of local and distal acupuncture points.

In conclusion, single-point acupuncture associated with physiotherapy improves function and alleviates pain in the shoulder to a greater degree than does physiotherapy as the sole treatment. This improvement is accompanied by a reduction in the consumption of analgesic medication. The clinical improvement was maintained during the 1-yr follow-up period. As this technique is simple and safe, it is recommendable as an auxiliary treatment for subacromial pathologies.

Conclusions

Painful shoulder is one of the most common disorders affecting the locomotor apparatus, and is frequently encountered both in primary healthcare clinics and by specialists. According to recent studies, acupuncture might be a viable therapeutic option for painful shoulder, but to date little evidence has been produced to corroborate its use in the treatment of this pathology, and calls have been made for further well-designed clinical trials to be carried out. Our study suggests that single-point acupuncture associated with physiotherapy improves function and alleviates pain in the shoulder to a greater degree than does physiotherapy as the sole treatment.

This improvement is accompanied by a reduction in the consumption of analgesic medication. The clinical improvement was maintained during the 1-yr follow-up period. As this technique is simple and safe, it is recommendable as an auxiliary treatment for subacromial pathologies.

Rheumatology key messages

- According to recent studies, acupuncture might be a viable therapeutic option for painful shoulder, but to date little evidence has been produced to corroborate its use in the treatment of this pathology.
- Single-point acupuncture associated with physiotherapy improves function and alleviates pain in the shoulder.
- This technique is recommendable as an auxiliary treatment for subacromial pathologies.

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