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Spinal Manipulation and Electrical Dry Needling in Patients With Subacromial Pain Syndrome: A Multicenter Randomized Clinical Trial

Nonsurgical interventions, including injections, medication, manual therapy, exercise, electrotherapy, and cognitive therapy, are recommended for first-line management of subacromial pain syndrome (SAPS).[14] Exercise is the principal treatment, although the most appropriate exercise regime (ie, type, dose, and load) is unclear.[54,70] Manual therapy combined with exercise may also be effective. However, the type (joint thrust manipulation/nonthrust mobilization, soft tissue mobilization) and location (extremity and/or spine) of manual therapy remain to be determined.[70,77]

OBJECTIVES: To compare the effects of spinal thrust manipulation and electrical dry needling (TMEDN group) to those of nonthrust peripheral joint/soft tissue mobilization, exercise, and interferential current (NTMEX group) on pain and disability in patients with subacromial pain syndrome (SAPS).

DESIGN: Randomized, single-blinded, multicenter parallel-group trial.

METHODS: Patients with SAPS were randomized into the TMEDN group (n = 73) or the NTMEX group (n = 72). Primary outcomes included the Shoulder Pain and Disability Index and the numeric pain-rating scale. Secondary outcomes included the global rating of change scale (GROC) and medication intake. The treatment period was 6 weeks, with follow-ups at 2 weeks, 4 weeks, and 3 months.

RESULTS: At 3 months, the TMEDN group experienced greater reductions in shoulder pain and disability ($P<.001$) compared to the NTMEX group. Effect sizes were large in favor of the TMEDN group. At 3 months, a greater proportion of patients within the TMEDN group achieved a successful outcome (GROC score of 5 or greater) and stopped taking medication ($P<.001$).

CONCLUSION: Cervicothoracic and upper-rib thrust manipulation combined with electrical dry needling resulted in greater reductions in pain, disability, and medication intake than nonthrust peripheral joint/soft tissue mobilization, exercise, and interferential current in patients with SAPS. These effects were maintained at 3 months. *J Orthop Sports Phys Ther 2021;51(2):xxx-xxx. Epub 28 Aug 2020. doi:10.2519/jospt.2021.9785*

KEY WORDS: *dry needling, exercise, impingement, manipulation, mobilization, shoulder*

It is unclear whether isolated thoracic spine thrust manipulation can change pain and disability in patients with SAPS.[6,30] However, manipulation to multiple spinal regions (cervical, upper thoracic, upper-rib articulations) may reduce pain and disability in patients with SAPS.[5,17,73,79] Addressing impairments in these spinal regions, rather than simply treating the primary area of pain, is consistent with the model of regional interdependence.[60,80,85] Continued study of the effectiveness of different manual therapy treatment techniques in patients with SAPS was recently recommended.[70]

The addition of electrotherapy, specifically interferential current (IFC), does not provide greater clinical benefit for patients with SAPS than nonsteroidal

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anti-inflammatory drugs,[65] cryotherapy,[65] exercise,[13,65] manual therapy,[13] and placebo.[14] However, IFC is still a preferred modality among some physical therapists for treating SAPS.[69] Interferential current therapy is an effective supplemental intervention for treating acute and chronic musculoskeletal pain,[12,27] and, when used in addition to exercise in patients with SAPS, IFC seems to have a positive effect on the mental component of quality of life.[84]

Needling therapies (trigger point dry needling[2,68] and acupuncture/electroacupuncture[31,42,47,53,63]) have inconsistent effects on pain and disability when compared with conventional orthopaedic therapy, placebo acupuncture, or subacromial corticosteroid injections in patients with shoulder pain.

No prior studies have directly compared the combined effects of thrust manipulation to the cervicothoracic spine/upper-rib articulations and dry needling versus a more common course of nonthrust joint/soft tissue extremity mobilization, exercise, and IFC in patients with SAPS. Notably, exercise therapy appears to be one of the more promising interventions in patients with SAPS[14,70,77]; however, we did not include exercise as part of the intervention for the experimental group, as it has a moderate between-group effect size in individuals with SAPS.[59,70,76] Including exercise would have prevented us from accurately determining the effectiveness and effect size of the relatively novel, standardized intervention alone, without an interaction effect.[20,23,46,57]

The purpose of this trial was to compare the effects of thrust manipulation to the cervicothoracic spine/upper-rib articulations and electrical dry needling (TMEDN group) to those of nonthrust peripheral joint/soft tissue mobilization, exercise, and IFC (NTMEX group). We hypothesized that patients in the TMEDN group would experience greater improvements in pain, disability, perceived recovery, and medication intake than patients in the NTMEX group.

METHODS

This randomized, single-blinded, multicenter parallel-group clinical trial was conducted following the Consolidated Standards of Reporting Trials (CONSORT) extension for pragmatic clinical trials.[90] The trial was approved by the Ethics Committee at Universidad Rey Juan Carlos, Alcorcón , Spain (URJC-DPTO 11-2017) and was prospectively registered at www.ClinicalTrials.gov (NCT03168477).

Participants

Consecutive individuals with SAPS from 14 outpatient physical therapy clinics in 12 US states (Arizona, Georgia, Maine, Maryland, Michigan, New York, North Carolina, Oklahoma, South Carolina, South Dakota, Tennessee, Texas) were screened for eligibility and recruited over a 22-month period (from June 15, 2017 to April 1, 2019). To be eligible, patients had to report a primary complaint of anterolateral shoulder pain lasting longer than 6 weeks and to have a positive Neer impingement test[32,43,66,74] (ie, pain with passive overpressure at full shoulder flexion with the scapula stabilized) and/or a positive Hawkins-Kennedy test[32,35,43,74] (ie, pain with passive internal rotation at 90° of shoulder and elbow flexion). In addition, patients had to report 1 or more of the following symptoms: (1) a painful arc with active shoulder elevation,[1,32] (2) pain with resisted shoulder external rotation at 90° of abduction,[1,32] or (3) pain with resisted shoulder abduction in the empty-can test position (ie, at 90° of shoulder abduction, 30° of horizontal adduction, and full internal rotation with the thumb down).[32,41,43] The exclusion criteria are described in **TABLE 1**.

Treating Therapists

Fourteen physical therapists delivered interventions in this trial. They had an average of 9.3 ± 6.8 years of clinical experience, had completed a 54-hour postgraduate certificate program that included practical training in electrical dry needling for SAPS, and were current students in a 60-hour postgraduate certificate program that included practical training in nonthrust joint/soft tissue mobilization and thrust manipulation techniques to the cervical, thoracic, upper-rib articulations, glenohumeral joint, acromioclavicular joint, and peri-scapular regions. All treating therapists were Fellows-in-Training in the American Physical Therapy Association (APTA)-accredited American Academy of Manipulative Therapy Fellowship in Orthopaedic Manual Physical Therapy program, had heterogeneous backgrounds in terms of prior manual therapy/orthopaedic training, and worked in private outpatient physical therapy practice. All participating therapists were required to

TABLE 1 Exclusion Criteria

- Steroid injection to the shoulder within the past 3 months
- Prior surgery to the neck, thoracic spine, or shoulder
- Red flags (ie, tumor, fracture, metabolic diseases, rheumatoid arthritis, osteoporosis, resting blood pressure greater than 140/90 mmHg, prolonged history of steroid use)
- History of shoulder dislocation, subluxation, fracture, adhesive capsulitis, or cervical or thoracic surgery
- History of a full-thickness rotator cuff tear
- Whiplash injury in the previous 6 weeks
- History of breast cancer on the involved side
- Isolated acromioclavicular joint pathology (ie, localized pain directly over the acromioclavicular joint)
- Evidence of cervical radiculopathy, radiculitis, or referred pain from the cervical spine
- One or more contraindications to dry needling or manual therapy
- Received treatment for shoulder pain within the previous 3 months
- Pending legal action or workers' compensation claim regarding symptoms
- Currently pregnant

study a manual of standard operating procedures and participate in a 6-hour training session with a principal investigator to standardize the protocol and treatment.

Randomization and Blinding

Following baseline examination, patients were randomly assigned to the TMEDN group or NTMEX group. Randomization was conducted using a computer-generated randomized table of numbers created by an independent statistician. Individual and sequentially numbered index cards with the random assignment were prepared, folded, and placed in sealed opaque envelopes for each of the 14 data-collection sites. The clinicians administering the self-report outcome questionnaires were blinded to the patient's treatment group assignment. It was not possible to blind patients or treating therapists.

Interventions

All participants received up to 12 treatment sessions, at a frequency of twice per week over a 6-week period. The interventions were designed to treat primary SAPS, as the majority of secondary impingement (ie, instability) was likely excluded with the inclusion and exclusion criteria for this study (**TABLE 1**). In either group, participants completed fewer treatment sessions when their symptoms resolved sooner.

The TMEDN group received an impairment-based manual therapy approach, using thrust manipulation directed primarily to the lower cervical (C4-C6), cervicothoracic (C7-T3), midthoracic (T4-T9), and upper-rib (1-3) articulations, as described in previous studies[5,17-19,74,79,81] and in **APPENDIX A** (available at www.jospt.org). In addition, the TMEDN group received up to 12 sessions of electrical dry needling for 20 minutes, using a standardized protocol of 8 obligatory points targeting intramuscular trigger points, musculotendinous junctions, teno-osseous attachments, and/or peri-articular tissue in the anterolateral subacromial, posterolateral subacromial, lateral brachium, and scapular regions (**FIGURE 1**). Additionally, placement of up to 6 needles in the upper thoracic paraspinal, periscapular, and glenohumeral regions was optional and based on the findings from passive motion testing, the presence of localized myofascial trigger points, and/or the presence of stiffness or pain during palpatory examination. Details regarding needle size, insertion site, angulation, depth, anatomical target, manipulation,[15,42,48,63,89] and electrical stimulation parameters[29,31,47,52,53,63,64] are summarized in **APPENDIX A**.

The NTMEX group received an impairment-based intervention of nonthrust peripheral mobilization (preferably grade III or IV) to the glenohumeral joint,[81] acromioclavicular joint,[81] and peri-scapular region,[3,74] as well as range-of-motion/stretching and strengthening exercises commonly used in patients with SAPS.[50,74,81] Grade III or IV joint mobilizations[37] were preferentially used to reduce hypomobility of the posterior capsule and surrounding tissue, improve glenohumeral arthrokinematics, and reduce symptoms.[38,44,51] Exercises and stretching were initially taught, supervised, and gradually progressed by the treating therapist, in conjunction with the stretching exercises and "phase 1" strengthening.[81] In addition, this group also received 8 to 15 minutes of soft tissue mobilization targeting the posterior and anterolateral shoulder region.[3,74] The treatment ended with 15 to 20 minutes of IFC, using 4 pads surrounding the subacromial space region.[25] Specific interventions are provided in **APPENDIX B** (available at www.jospt.org).

Home-based exercise in patients with SAPS is as effective as supervised exercise.[33] We did not include a home exercise program for the NTMEX group, as it would have unfairly increased the treatment dosage of the comparison group beyond that of the experimental group. Up to 70% of patients may be noncompliant with home-based exercise programs.[21]

Outcome Measures

The primary outcomes were the Shoulder Pain and Disability Index (SPADI)[55] and the numeric pain-rating scale (NPRS),[62] assessed at baseline, 2 weeks, 4 weeks, and 3 months (the primary end point). Secondary outcomes were the global rating of change scale (GROC),[40] assessed at 2 weeks, 4 weeks, and 3 months, and medication intake, assessed at baseline and 3 months after the first treatment session. Each outcome measure and its psychometric properties are described in **APPENDIX C** (available at www.jospt.org).

Treatment Side Effects

Patients were asked to report any adverse events. We defined adverse events as sequelae of 1-week duration, with any symptom perceived as distressing and unacceptable to the patient and requiring further treatment.[8,67] The treating therapists and patients in the TMEDN group were instructed to pay particular attention to the presence of ecchymosis and postneedling soreness.

Sample-Size Determination

Our sample-size calculations were based on detecting a between-group effect size of 0.58 in shoulder-related disability (SPADI) at 3 months, using a 2-tailed test, an alpha level of .05, and a desired power (β) of 90%. The estimated desired sample size was at least 65 participants per group. We anticipated a dropout rate

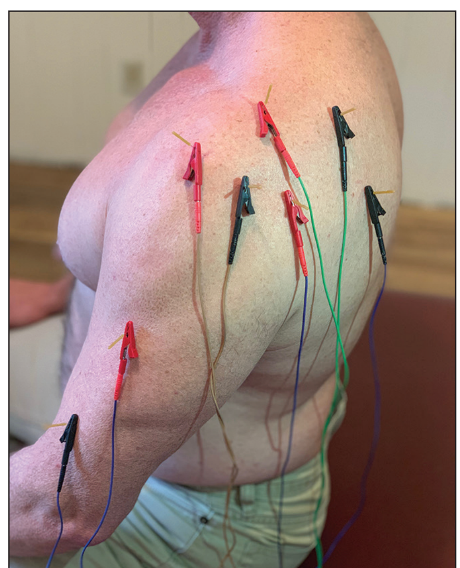

FIGURE 1. Standardized protocol (8 needles) for electrical dry needling for subacromial pain syndrome.

of 10%. Therefore, 70 participants were required for each group.

Statistical Analysis

Statistical analysis was performed using SPSS Version 26.0 (IBM Corporation, Armonk, NY), according to the intention-to-treat principle. Means, standard deviations, and/or 95% confidence intervals (CIs) were calculated for each variable. The Kolmogorov-Smirnov test revealed a normal distribution of the variables (P>.05). Baseline demographic and clinical variables were compared between groups using independent Student t tests for continuous data and chi-square tests of independence for categorical data.

The effects of treatment on the SPADI and NPRS were each examined with a 2-by-4 mixed-model analysis of covariance (ANCOVA), with treatment group (TMEDN versus NTMEX) as the between-subjects factor and time (baseline, 2 weeks, 4 weeks, and 3 months) as the within-subjects factor. Separate ANCOVAs were performed with either the SPADI or the NPRS as the dependent variable. Age and duration of symptoms were entered as covariates.

For each ANCOVA, the main hypothesis of interest was the 2-way interaction (group by time), with a Bonferroni-corrected alpha of .0125 (4 time points). We used chi-square tests to compare self-perceived improvement on the GROC and changes in medication intake. To enable comparison of between-group effect sizes, standardized mean differences (SMDs) in score were calculated by dividing mean score differences between groups by the pooled standard deviation. Number needed to treat (NNT) was calculated using each definition for a successful outcome (a GROC score improvement of 5 or greater[40] at 3 months and a 50% improvement from baseline to 3 months on the SPADI[55]).

RESULTS

Between June 2017 and April 2019, 375 consecutive patients with SAPS were screened for eligibility (**FIGURE 2**), of whom 145 (38.7%) satisfied all the inclusion criteria, agreed to par-

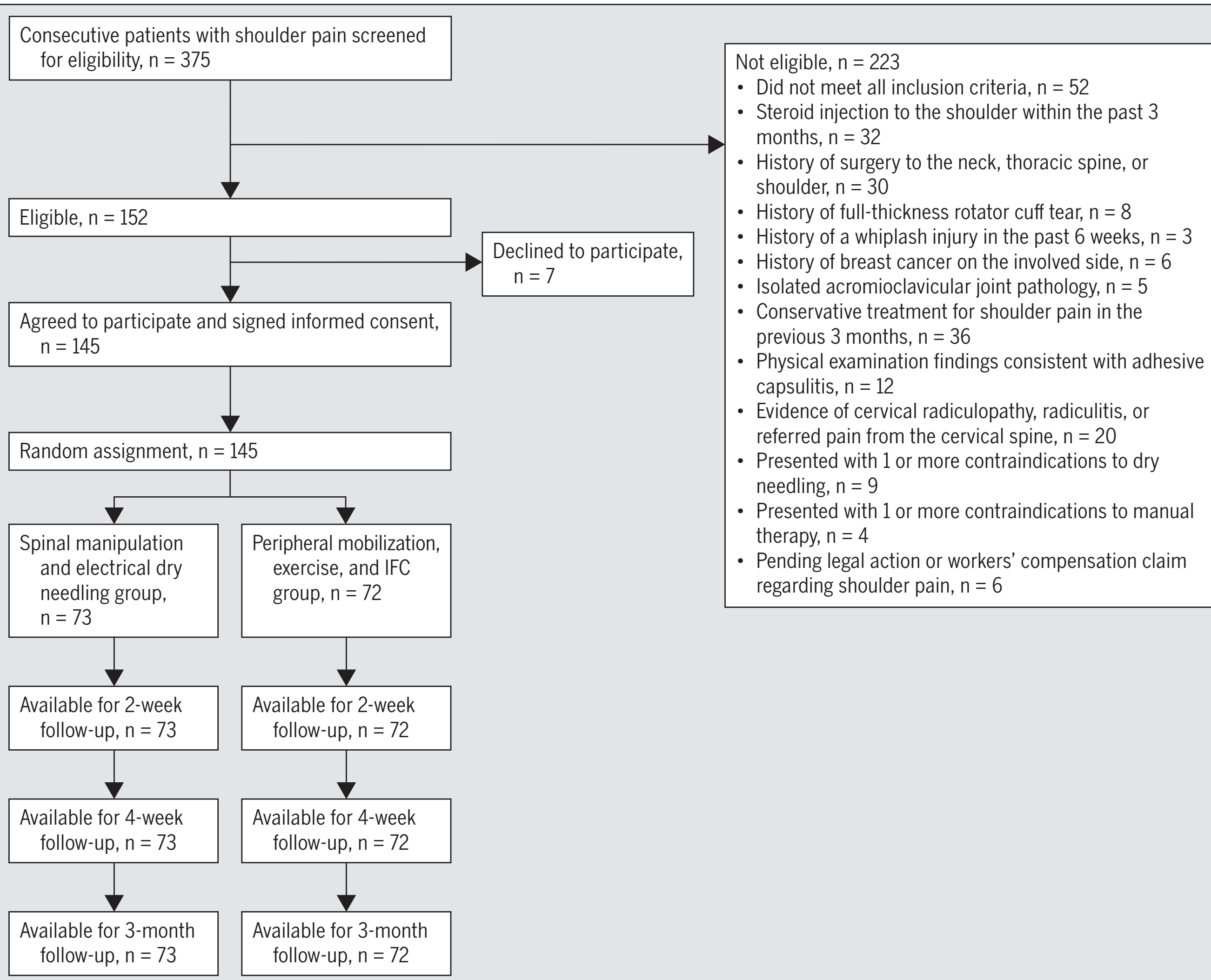

FIGURE 2. CONSORT flow diagram of patient recruitment and retention. Abbreviation: IFC, interferential current.

ticipate, and were randomly allocated into the TMEDN (n = 73) group or the NTMEX (n = 72) group. Baseline characteristics were similar for all variables (**TABLE 2**). No patients were lost at any of the follow-up periods in either group. None of the participants in any group reported receiving other interventions during the study. There was no significant difference (*P* = .852) between the mean number of completed treatment sessions for the TMEDN group (mean, 10.1) and the NTMEX group (mean, 10.0).

Thirty-seven patients assigned to the TMEDN group (50.7%) experienced postneedling muscle soreness and 15 (20.5%) experienced mild bruising (ecchymosis), which most commonly resolved spontaneously within 48 hours and 2 to 4 days, respectively. Two patients (2.7%) in the TMEDN group experienced drowsiness, headache, or nausea, which spontaneously resolved within several hours. No adverse events were reported in the NTMEX group.

Adjusting for baseline outcomes, there was a significant group-by-time interaction for shoulder-related disability (SPADI: F = 21.889, *P*<.001) (**TABLE 3**). Patients in the TMEDN group experienced greater reductions in shoulder-related disability at 4 weeks (mean change, –10.6; 95% CI: –14.8, –6.4; *P*<.001) and 3 months (mean change, –17.9; 95% CI: –22.4, –13.5; *P*<.001) than those in the NTMEX group (**FIGURE 3**). Between-group effect sizes for the SPADI were moderate (SMD, 0.8) at 4 weeks and large (SMD, 1.1) at 3 months after the first treatment session, in favor of the TMEDN group.

There was a significant group-by-time interaction for shoulder pain intensity (NPRS: F = 21.239, *P*<.001) (**FIGURE 4**), in favor of the TMEDN group (**TABLE 3**). For the NPRS, between-group effect sizes were also moderate (SMD, 0.7) at 4 weeks and large (SMD, 1.1) at 3 months after the first treatment session, in favor of the TMEDN group.

Significantly (χ^2 = 25.710, *P*<.001) more patients in the TMEDN group (n = 54, 74%) ceased taking medication for their pain compared to the NTMEX group (n = 23, 32%) at 3 months. Based on the cutoff score of +5 or greater on the GROC,[40] significantly (χ^2 = 31.029, *P*<.001) more patients (n = 52, 71%)

TABLE 2 Baseline Characteristics by Treatment Assignment[a]

Baseline Variable	Spinal Manipulation Plus Electrical Dry Needling (n = 73)	Peripheral Mobilization Plus Exercise Plus IFC (n = 72)
Sex, n		
Male	37	34
Female	36	38
Age, y	46.2 ± 15.6	47.8 ± 15.8
Weight, kg	77.9 ± 15.7	76.7 ± 17.9
Height, cm	172.4 ± 8.8	171.6 ± 9.6
Duration of symptoms, wk	104.0 ± 174.2	106.8 ± 183.8
Category of symptom duration, n		
Subacute (6-12 wk)	13	15
Chronic (>12 wk)	60	57
Medication intake, n (%)[b]		
Not at all	4 (5.5)	15 (20.8)
Once a week	25 (34.2)	14 (19.4)
Once every couple of days	25 (34.2)	28 (38.9)
Once or twice a day	18 (24.7)	12 (16.7)
3 or more times a day	1 (1.4)	3 (4.2)
Treatment sessions, n	10.1 ± 2.2	10.0 ± 2.1
Shoulder pain intensity (NPRS)[c]	5.4 ± 1.4	5.2 ± 1.6
Disability (SPADI)[d]	44.9 ± 14.6	43.3 ± 16.2

Abbreviations: IFC, interferential current; NPRS, numeric pain-rating scale; SPADI, Shoulder Pain and Disability Index.
[a]*Values are mean ± SD unless otherwise indicated.*
[b]*The number of times the patient had taken prescription or over-the-counter analgesic or anti-inflammatory medication in the past week for shoulder pain.*
[c]*Lower scores indicate less pain (0-10).*
[d]*Lower scores indicate greater function (0-100).*

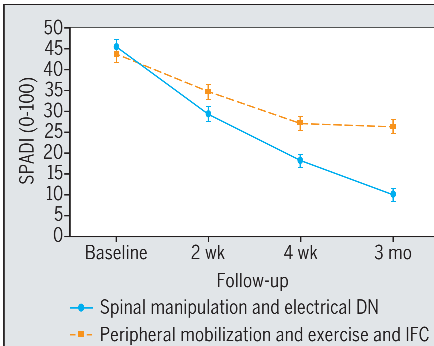

FIGURE 3. Evolution of shoulder-related disability throughout the course of the study, stratified by randomized treatment assignment. Values are mean and standard error. All between-group changes were significant (*P*<.001). Abbreviations: DN, dry needling; IFC, interferential current; SPADI, Shoulder Pain and Disability Index.

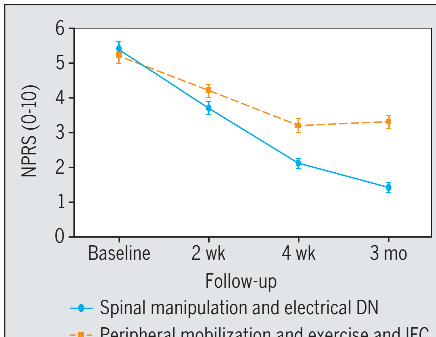

FIGURE 4. Evolution of shoulder pain intensity throughout the course of the study, stratified by randomized treatment assignment. Values are mean and standard error. All between-group changes were significant (*P*<.01). Abbreviations: DN, dry needling; IFC, interferential current; NPRS, numeric pain-rating scale.

within the TMEDN group achieved a successful outcome compared to the NTMEX group (n = 18, 25%) at 3 months (**TABLE 4**). The NNT was 2 (95% CI: 1.7, 3.1), in favor of the TMEDN group. Likewise, based on a 50% improvement from baseline to 3 months in shoulder-related disability on the SPADI, the NNT was 1.8 (95% CI: 1.5, 2.3), in favor of the TMEDN group.

There was no significant effect of the duration of symptoms on shoulder-related disability (SPADI: F = 1.115, P = .293, η_p^2 = 0.008) or shoulder pain (NPRS: F = 2.408, P = .123, η_p^2 = 0.017). The duration of symptoms accounted for 1% of the variance in the SPADI and 2% of the variance in the NPRS.

DISCUSSION

A mean of 10 sessions of thrust manipulation to the cervicothoracic spine/upper-rib articulations and electrical dry needling (TMEDN) resulted in greater improvements in shoulder pain intensity, shoulder-related disability, and medication intake in comparison to NTMEX. For disability (SPADI), effect sizes were moderate and large at 4 weeks and 3 months, respectively, in favor of the TMEDN group. The between-group difference for change in shoulder pain intensity at 3 months, as measured by the NPRS, was also large and exceeded the reported minimal clinically important difference (MCID) for shoulder pain.[24,61,62] For disability (SPADI), the point estimate for the between-group difference at 3 months (17.9 points) exceeded the respective MCID in patients with shoulder pain.[36,75] For every 2 patients treated with TMEDN, 1 additional patient with SAPS achieved clinically important reductions in disability and “moderate” to “large” changes in self-perceived improvement ratings at 3 months.

Our results are similar to previous trials that found thrust manipulation to the cervicothoracic spine and rib articulations to be effective in patients with shoulder pain and SAPS.[5,17,73] Nevertheless, a recent multicenter randomized clinical trial[53] (n = 227) found that the addition of acupuncture or electroacupuncture was no more effective than exercise alone in the treatment of individuals with SAPS. However, in contrast to the current study, Lewis et al[53] included patients with full-thickness and/or massive irreparable rotator cuff tears, and therefore used a much broader and nonspecific definition of SAPS than other trials[2,7,31,32,47,63,68] and diagnostic guidelines.[14]

Prior trials on dry needling for shoulder pain investigated intramuscular trigger point dry needling and needle pistoning techniques, resulting in inconsistent outcomes for meaningful changes in pain and disability.[2,68] In contrast, the treatment protocol of the current trial utilized bilateral and/or unilateral rotation manipulation[4,10] of multiple needles[56] left in situ, combined with electrical stimulation[9,34,52,58] to intramuscular, musculotendinous, teno-osseous,

TABLE 3 Within-Group and Between-Group Mean Scores by Randomized Treatment Assignment[a]

Outcome	Spinal Manipulation Plus Electrical Dry Needling (n = 73)	Peripheral Mobilization Plus Exercise Plus IFC (n = 72)	Between-Group Difference[b]	SMD	*P* Value
SPADI (disability)[c]					
Baseline	44.9 ± 14.6 (41.6, 48.4)	43.3 ± 16.2 (39.5, 47.1)			
2 wk	29.0 ± 16.9 (25.1, 32.9)	34.4 ± 16.3 (30.6, 38.2)			
Change: baseline to 2 wk[b]	–15.9 (–18.8, –13.2)	–8.9 (–11.4, –6.3)	–7.1 (–10.9, –3.3)		<.001
4 wk	18.0 ± 13.3 (14.9, 21.2)	26.9 ± 15.5 (23.3, 30.6)			
Change: baseline to 4 wk[b]	–26.9 (–30.2, –23.7)	–16.3 (–18.9, –13.7)	–10.6 (–14.8, –6.4)	0.8	<.001
3 mo	9.9 ± 10.1 (7.6, 12.3)	26.1 ± 17.6 (22.0, 30.3)			
Change: baseline to 3 mo[b]	–35.1 (–38.3, –31.9)	–17.1 (–20.3, –14.0)	–17.9 (–22.4, –13.5)	1.1	<.001
NPRS (shoulder pain intensity)[d]					
Baseline	5.4 ± 1.4 (5.1, 5.7)	5.2 ± 1.6 (4.9, 5.6)			
2 wk	3.7 ± 1.8 (3.3, 4.1)	4.2 ± 1.7 (3.8, 4.6)			
Change: baseline to 2 wk[b]	–1.7 (–2.1, –1.3)	–1.0 (–1.3, –0.7)	–0.7 (–1.2, –0.2)		.007
4 wk	2.1 ± 1.7 (1.7, 2.5)	3.2 ± 1.7 (2.8, 3.6)			
Change: baseline to 4 wk[b]	–3.2 (–3.6, –2.9)	–2.0 (–2.4, –1.7)	–1.2 (–1.8, –0.7)	0.7	<.001
3 mo	1.4 ± 1.6 (1.0, 1.7)	3.3 ± 1.9 (2.9, 3.8)			
Change: baseline to 3 mo[b]	–4.0 (–4.4, –3.6)	–1.9 (–2.3, –1.5)	–2.1 (–2.7, –1.6)	1.1	<.001

Abbreviations: IFC, interferential current; NPRS, numeric pain-rating scale; SMD, standardized mean difference; SPADI, Shoulder Pain and Disability Index.
[a]*Values are mean ± SD (95% confidence interval) unless otherwise indicated.*
[b]*Values are mean (95% confidence interval).*
[c]*Lower scores indicate greater function (0-100).*
[d]*Lower scores indicate less pain (0-10).*

periosteal, and peri-articular tissues of the shoulder complex.[15,16,49,78,86]

Although the terminology, theoretical constructs, and philosophies of "dry needling" and "acupuncture" differ, they are often considered to be in the same category of intervention,[28,72,82,83] as both use thin monofilament needles without injectate to treat neuromusculoskeletal conditions.[15,82,83,88] We chose to include "electrical dry needling" as part of the experimental group, as opposed to "dry needling" alone, because there may be superior analgesia obtained when treating pain with electroacupuncture compared to manual acupuncture alone.[9,34,52,58]

There are several neurophysiologic mechanisms that may explain the superior analgesic effects of electroacupuncture over manual acupuncture. Notably, when compared with manual acupuncture, electroacupuncture produced a more widespread functional magnetic resonance imaging signal increase in the anterior middle cingulate cortex, which has been implicated in the affective dimension of pain by diminishing pain unpleasantness.[64] Furthermore, electroacupuncture may block the local release of inflammatory cytokines (ie, interleukin-1β and tumor necrosis factor-α) in the synovia of joints[39] and the systemic release of inflammatory factors in the peri-aqueductal gray of the brain stem,[87] thereby reducing pain intensity.

Limitations

There are 4 important limitations to our trial. First, we excluded exercise from the experimental group (TMEDN). Exercise appears to be one of the more promising interventions in patients with SAPS.[14,70,77] We did not include exercise as part of the intervention for the experimental group because it has already been shown to have a moderate between-group effect size in individuals with SAPS.[59,76] We chose not to add a relatively novel, standardized intervention (TMEDN) to exercise, an intervention known to likely be effective in SAPS,[59,70,76] so that we could determine the effectiveness and between-group effect size of the new treatment alone, without an interaction effect.[20,23,46,57]

Second, we did not prescribe a home exercise program for either group in this study, as nonadherence has been reported in up to 70% of patients,[21] exercise diaries appear to be unreliable,[71] and many patients fail to appropriately dose or correctly perform their home exercise program.[11,22]

Third, we did not use a placebo needling or control group. Although we recognize the use of a placebo needling group as an ideal situation,[45] our goal was to compare the novel intervention (TMEDN) to a more common physical therapy intervention (NTMEX) to more accurately determine the new treatment's effect size,[20,23,57] without the potential for an inflated between-group effect size.[23,46] Trials measure relative efficacy of a treatment compared to a control, placebo, or usual care.[45] We believe the question of whether the novel intervention (TMEDN) works any better, or provides any different outcome, than a common physical therapy intervention (NTMEX) is meaningful to clinicians and to patients with SAPS.[26,45] Verum acupuncture is superior to placebo acupuncture in patients with SAPS.[31,47,63] A recent secondary analysis of an individual patient data meta-analysis of 29 trials (n = 19 827) of acupuncture for chronic pain concluded that real acupuncture was superior to sham needling, irrespective of the subtype of control or sham procedure (penetrating or nonpenetrating).[57]

Fourth, there is a risk of treatment bias secondary to all treating therapists being associated with the same postgraduate fellowship program in orthopaedic manual physical therapy. However, treatment bias is not uncommon in manual therapy trials that require a very specific and advanced skill set.

TABLE 4 Self-perceived Improvement Measured With the Global Rating of Change[a]

Global Rating of Change (–7 to +7)	Spinal Manipulation Plus Electrical Dry Needling (n = 73)	Peripheral Mobilization Plus Exercise Plus IFC (n = 72)
2 wk after first treatment session		
Moderate changes		
+4	11 (15.1)	8 (11.1)
+5	11 (15.1)	5 (6.9)
Large changes		
+6	7 (9.6)	1 (1.4)
+7	0 (0.0)	0 (0.0)
4 wk after first treatment session		
Moderate changes		
+4	17 (23.3)	12 (16.7)
+5	20 (27.4)	7 (9.7)
Large changes		
+6	13 (17.8)	3 (4.2)
+7	8 (11.0)	4 (5.6)
3 mo after first treatment session		
Moderate changes		
+4	11 (15.1)	7 (9.7)
+5	17 (23.3)	8 (11.1)
Large changes		
+6	17 (23.3)	6 (8.3)
+7	18 (24.7)	4 (5.6)

Abbreviation: IFC, interferential current.
[a]*Values are n (percent).*

CONCLUSION

Patients with SAPS who received cervicothoracic/upper-rib thrust manipulation and electrical dry needling experienced greater improvements in shoulder pain, disability, and medication intake compared to patients who received peripheral joint/soft tissue nonthrust mobilization, exercise, and interferential electrotherapy. ◉

KEY POINTS

FINDINGS: In patients with subacromial pain syndrome (SAPS), the combination of thrust manipulation to the cervicothoracic/upper-rib articulations and electrical dry needling resulted in greater improvements in shoulder pain, disability, and medication intake compared to patients who received a treatment of exercise, peripheral nonthrust joint/soft tissue mobilization, and interferential electrotherapy.

IMPLICATIONS: The addition of cervicothoracic/upper-rib thrust manipulation and electrical dry needling to a more commonly used treatment program of peripheral joint mobilization and exercise may benefit patients with SAPS, and could be considered in the clinical setting and for future studies.

CAUTION: The results may not be generalizable to other shoulder diagnoses, manual therapies, or dry needling techniques. Further study is needed to establish a comprehensive treatment strategy for SAPS.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: Drs Dunning, Butts, and Fernández-de-las-Peñas participated in the conception, design, data acquisition, statistical analyses, data interpretation, and drafting and revision of the manuscript. Drs Young, Arias-Buría, and Garcia were involved in the data interpretation and drafting and revision of the manuscript. Drs Walsh, Goult, and Gillett were involved in data collection and revision of the manuscript. All authors read and approved the final version of the manuscript.

DATA SHARING: All data relevant to the study are included in the article or are available as online-only appendices.

PATIENT AND PUBLIC INVOLVEMENT: There was no patient and/or public involvement in the design, conduct, interpretation, and/or translation of the research.

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APPENDIX A

TMEDN GROUP

Description of TMEDN Interventions

Thrust Manipulation Techniques for SAPS

Patients randomized to the TMEDN group received manual therapy consisting of thrust manipulation (ie, HVLA thrust manipulation techniques), defined as a localized, single, quick, and decisive movement that has a small amplitude and short duration (ie, 80-200 milliseconds) and is often accompanied by multiple cavitation sounds. Thrust manipulation techniques targeted 4 regions: the lower cervical spine, the cervicothoracic junction, the thoracic spine, and the adjacent ribs. While each treatment session had to include manipulative techniques in 1 or more of these 4 areas, the technique chosen and areas targeted were impairment based. That is, they were chosen by the treating physical therapist based on the presentation of each individual patient, based on the findings from passive and active motion testing, the presence of localized myofascial trigger points, and/or the presence of stiffness or pain during palpatory examination. The following manipulation techniques were used during this study.

Cervical (C2-C7) HVLA Thrust Manipulation (Supine)

The manipulation targeting motion segments in the C2-C7 region was performed with the patient in supine. For this technique, the anterolateral aspect of the therapist's proximal, middle, or distal phalanx of the index finger contacted the posterolateral articular pillar of the target segment using a "cradle hold." For the target segment, localization of the forces was achieved using extension (C2-3, C3-4), neutral (C4-5), or flexion (C5-6, C6-7) positions of the cervical spine, along with ipsilateral sidebending and contralateral translation. While maintaining this position, the therapist performed a single HVLA thrust manipulation using right (or left) rotation in an arc toward the space between the underside zygoma and the angle of the mandible.

Cervicothoracic Junction (C7-T3) HVLA Thrust Manipulation (Prone)

A single "lateral break" HVLA thrust manipulation directed to the cervicothoracic junction (C7-T3), with the patient prone, was performed. The T1-2 level was the target because this segment is in the center of the 3 articulations (ie, C7-T1, T1-2, T2-3) that are considered to be primarily affected by the manual forces during prone HVLA thrust manipulations to the cervicothoracic junction. For this technique, the short or lower lever was produced by having the therapist's proximal phalanx, metacarpal, web space, and thumb of the right hand contact the superomedial aspect of the patient's right shoulder girdle. The long or upper lever was manufactured by having the therapist place the heel and palm of his left hand over the temporal region of the patient's lateral cranium. To localize the forces to the left T1-2 articulation, secondary levers of extension, lateral flexion, translation, and minimal rotation were used. While maintaining the secondary levers, the therapist performed a single HVLA thrust manipulation using the simultaneous delivery of the thrusting primary levers of lateral flexion from the upper lever and lateral translation from the lower lever, that is, a lateral break. This was repeated using the same procedure but directed to the right T1-2 articulation.

Upper Thoracic (T1-T3) HVLA Thrust Manipulation (Supine)

The manipulation targeting motion segments in the T1-T3 region was performed with the patient in supine. For this technique, the patient held her or his arms and forearms across the chest, with the elbows aligned in a superoinferior direction. The therapist contacted the transverse processes of the lower vertebrae of the target motion segment with the thenar eminence and middle phalanx of the third digit. The upper lever was localized to the target motion segment by adding rotation away from and sidebending toward the therapist, while the underside hand used pronation and radial deviation to achieve rotation toward and sidebending away moments, respectively. The space inferior to the xiphoid process and costochondral margin of the therapist was used as the contact point against the patient's elbows to deliver a manipulation in an anterior-to-posterior direction.

Upper Ribs (R1-R3) HVLA Thrust Manipulation (Supine)

For this technique, the patient's arms were folded horizontally across the chest. Contact was made onto the second and/or third ribs by hooking the operator's volar aspect of the first carpometacarpal joint perpendicular to the upper ribs, just lateral to transverse processes of T2-3 but medial to the respective rib angles. The operator's underside forearm was prepositioned in mid pronation/supination, and to tension the costotransverse articulation, a caudad-directed "pulling down" on the second rib was initiated as the patient was rolled over onto the back. Cephalad and posterior traction was introduced via the operator's own costochondral margin against the patient's forearms. Gentle posterior compression toward the table over the lateral infraclavicular and lateral pectoral region was provided. The patient was then asked to lift the head off the pillow, and at that moment, the following 3 levers of HVLA thrust were simultaneously delivered: (1) a cephalad and posterior traction thrust via the operator's epigastric region, (2) an anterior-to-posterior compression thrust over the infraclavicular and superolateral pectoral region with the operator's cephalad hand, and (3) a pronation and caudad traction thrust of the operator's caudad or underside hand.

Midthoracic Facet (T4-T9) HVLA Thrust Manipulation (Supine)

The patient is supine, with the arms across the chest in a "V" and with the far arm on top. Contact is made over the right and left transverse processes of the lower vertebra of the target motion segment. The applicator is the pisiform and scaphoid tubercle of the operator's underside hand, while the forearm is essentially vertical to avoid the scapula and the fingers point cephalad. The patient's head and neck are gently flexed and are carefully rested on the operator's forearm. Flexion of the thoracic spine is introduced to focus the forces and fulcrum over the desired target segment. Via the operator's infraxiphoid abdominal contact over the patient's elbows on the chest, an HVLA thrust manipulation is delivered in a cephalad and posterior direction.

Midthoracic Ribs (R4-R9) HVLA Thrust Manipulation (Prone)

The manipulation targeting ribs in the midthoracic (R4-R9) region was performed with the patient in prone. On the ipsilateral side of the spine, the therapist

APPENDIX A

contacted the transverse process 1.5 interspinous spaces below the target with the hypothenar eminence. In order to remove the skin-myofascial interface, the therapist took up the slack in the cephalad direction. On the contralateral side of the spine, the therapist contacted the target rib with the hypothenar eminence. With the hypothenar eminence parallel with the rib, the therapist removed the skin-myofascial interface by taking up the slack laterally. Once the forearms were perpendicular to the patient's trunk, the thrust was delivered in a posterior-to-anterior direction with both hands equally.

Electrical Dry Needling Protocol for SAPS

Technique Description

The technique is performed with the patient in sitting or sidelying. Sterilized, disposable stainless steel acupuncture needles were used, with 4 sizes: 0.25 × 30 mm, 0.30 × 40 mm, 0.30 × 50 mm, or 0.30 × 60 mm. The surface of the glenohumeral and scapulothoracic region was cleaned with alcohol. The depth of needle insertion ranged from 15 mm to 55 mm, depending on the point selected (intramuscular, musculotendinous junction, teno-osseous attachment, periosteal, peri-articular tissue) and the patient's constitution (ie, size and bone depth, muscle and/or connective tissue thickness). Following insertion, needles were manipulated bidirectionally to elicit a sensation of aching, tingling, deep pressure, heaviness, or warmth. The needles were then left in situ for 20 minutes, with electric stimulation (ES-160 electrostimulator; ITO Co, Ltd, Kawaguchi, Japan) in pairs to up to 8 of the needles using a low-frequency (2 Hz), moderate-pulse-duration (250 microseconds), biphasic continuous waveform at an intensity described by the patient as "moderate."

The surface of the glenohumeral and scapulothoracic region was cleaned with alcohol. For each treatment session, and based on the patient's report of sensitivity or area of pain and/or the presence of trigger points for a given region, needles were inserted in 8 obligatory locations over the subacromial, scapular, and brachium regions (**FIGURE 1**). Additionally, placement of up to 6 needles in the upper thoracic paraspinal, peri-scapular, and glenohumeral regions was optional and based on the findings from passive motion testing, the presence of localized myofascial trigger points, and/or the presence of stiffness or pain during palpatory examination.

Obligatory subacromial, scapular, and brachium points:

1. Medial insertion 4 finger breadths proximal to the lateral epicondyle, over the lower lateral aspect of the brachium, anterior to the humerus within the brachialis muscle
2. Medial insertion 3 finger breadths caudal to the anterior axillary fold, over the upper lateral brachium, within the depression near the distal attachment of the deltoid muscle
3. Posteromedial and slightly inferior insertion within the depression between the anterior and middle deltoid muscles over the anterolateral subacromial region—the teno-osseous attachment of the supraspinatus over the upper facet of the greater tubercle of the humerus
4. Superior-to-inferior insertion, just over 1 cm medial to the tip of the triangle made by the inner borders of the distal clavicle and the acromion, through the upper trapezius muscle and subdeltoid/subacromial bursa, targeting the musculotendinous junction of the supraspinatus
5. Anteromedial and slightly inferior insertion within the depression between the middle and posterior deltoid muscles over the posterolateral subacromial region
6. Caudal, slightly lateral and anterior insertion superior to the midpoint of the spine of the scapula in the supraspinous fossa—common trigger point within the supraspinatus muscle
7. Perpendicular insertion 1 finger breadth inferior to the posterior acromion directly over the glenohumeral joint margin, targeting the musculotendinous junction of the infraspinatus muscle
8. Perpendicular insertion one third of the distance from the middle of the spine of the scapula to the inferior angle of the scapula, targeting common myofascial trigger points in the infraspinatus muscle

Optional upper thoracic, peri-scapular, and glenohumeral points:

9. Anteromedial and slightly caudal insertion, 2 finger breadths lateral to the midline and lower border of the T1, T2, and/or T3 spinous processes within myofascial trigger points of the paraspinal aspects of the middle trapezius, rhomboid major and minor, and serratus posterior superior muscles
10. Posterior-to-anterior insertion, just less than 1 finger breadth lateral to the middle of the tip of the spinous processes of T1, T2, and/or T3, targeting myofascial trigger points of the paraspinal aspects of the trapezius, rhomboid major and minor, serratus posterior superior, erector spinae, and thoracic multifidus muscles
11. Posterior-to-anterior insertion, midway between the C7 spinous process and the acromion within the upper trapezius muscle—a common myofascial trigger point of the shoulder girdle region
12. Oblique insertion lateral and slightly anterior, just medial to the vertebral border of the scapula and approximately 4 finger breadths lateral to the midline of the T2, T3, T5, and T7 spinous processes
13. Oblique insertion lateral and slightly anterior, 4 finger breadths lateral to the midline of the T1 spinous process
14. Oblique insertion lateral and slightly anterior, 3 finger breadths lateral to the C7 spinous process
15. Anteromedial insertion 4 finger breadths inferior to the tip of the posterolateral acromion, along the posterior border of the deltoid muscle
16. Posterior insertion halfway between the coracoid process and lesser tubercle of the humerus—superior, middle, and inferior aspects of the anterior glenohumeral joint line and/or head of the humerus
17. Posterior-to-anterior insertion 2 finger breadths superior to the posterior axillary crease, targeting the teres major muscle

Abbreviations: HVLA, high velocity, low amplitude; SAPS, subacromial pain syndrome; TMEDN, spinal thrust manipulation and electrical dry needling.

APPENDIX B

NTMEX GROUP

Description of NTMEX Interventions

Nonthrust Mobilization Techniques (Grade III/Preferably IV)

The mobilization techniques used in the NTMEX group have been outlined and described in detail by Tate et al[81] and Rhon et al.[74] Please see these studies for a detailed written description, along with pictorial representations, of the mobilization techniques utilized. The nonthrust mobilization techniques chosen and the specific areas targeted were impairment based for each individual patient. That is, they were chosen by the treating physical therapist based on the presentation of each individual patient, based on the findings from passive and active motion testing, the presence of localized myofascial trigger points, and/or the presence of stiffness or pain during palpatory examination. Below is a list of nonthrust mobilization techniques used in the study.

- Glenohumeral posterior glide
- Glenohumeral posterior glide with active elevation (Mobilization With Movement)
- Cross-body posterior shoulder mobilization
- Internal rotation passive stretching
- Glenohumeral inferior glide
- Acromioclavicular joint (optional)
  - Anterior-to-inferior glide of clavicle (seated or supine)
- Peri-scapular mobilizations
  - Scapulothoracic elevation/depression
  - Scapulothoracic protraction/retraction

Soft Tissue Nonthrust Mobilization Techniques

The soft tissue mobilization techniques used to the shoulder complex have not been standardized in any prior study on impingement syndrome, but have been reported previously.[3,74] The soft tissue mobilization techniques chosen and the specific areas targeted were impairment based for each individual patient. That is, they were chosen by the treating physical therapist based on the presentation of each individual patient, based on the findings from passive and active motion testing, the presence of localized myofascial trigger points, and stiffness and/or pain during palpatory examination. In this study, the soft tissue mobilization techniques were performed pragmatically, based on patient presentation, and included the following areas.

- Supraspinatus fossa (belly) and insertion
- Proximal biceps tendon
- Infraspinatus belly
- Teres minor belly
- Sternocleidomastoid
- Upper trapezius
- Pectoralis minor
- Scalenes

Exercise Protocol

The exercise prescription included stretching and strengthening exercises, similar to those described in the "phase 1" treatment outlined by Tate et al.[81] The specific exercises chosen and the specific areas targeted were impairment and dysfunction based for each individual patient. That is, they were chosen by the treating physical therapist based on the presentation of each individual patient, based on the findings from passive and active motion testing and the presence of stiffness or pain during examination.

Range-of-Motion Exercise Protocol for SAPS

Technique Description

Range-of-motion exercises were progressed from pendulums to active-assisted movements and, finally, to active range of motion. The goal for all range-of-motion exercises was to maintain a pain-free range of motion. While 3 sets of pendulums were performed for 30 to 45 seconds, all other range-of-motion exercises were performed for 3 sets of 10 repetitions.

1. Pendulum exercises: from a supported position in standing, the patient bends forward and dangles the painful upper extremity while performing clockwise/counterclockwise circles and forward/backward movements
2. Posture exercises: from a standing position, the patient leans back with the hands on the hips and holds the position to facilitate proper posture
3. Scapular retractions: from a sitting or standing position, the patient pulls the shoulder blades back and together, while keeping the shoulders in an elevated or "shrugged" position
4. Pole-assisted active range of motion: from a supine or standing position, the patient uses a pole or cane to actively assist the painful upper extremity with the healthy upper extremity into shoulder flexion, external rotation, and abduction
5. Active shoulder abduction: from a standing position, the patient performs active movements into shoulder abduction in a pain-free range, without shrugging the shoulders

APPENDIX B

Flexibility Exercise Protocol for SAPS

Technique Description

Three sets of each stretch were performed, with a 30-second hold and a 10-second rest between sets. The goal of all stretches was to cause slight discomfort, without reproducing symptoms associated with SAPS.

1. Anterior shoulder stretch: from a standing position, the patient places the hands level with the shoulders on either side of a door frame or corner of the room, while shifting the body forward until a strong but comfortable stretch can be felt in front of the shoulder
2. Posterior shoulder stretch: from a standing or seated position, the patient moves the painful arm across the front of the body while using the healthy arm to pull it toward the chest until a strong but comfortable stretch can be felt in the back of the shoulder

Strengthening Exercise Protocol for SAPS

Technique Description

The following strengthening exercises were performed with 3 sets of 10 repetitions. As strength improved, resistance was added (yellow, red, green, blue bands), following phase 1 strength/motor control exercises reported by Tate et al.[81] The goal of all strengthening exercises was to cause muscle fatigue and slight discomfort associated with training, without reproducing symptoms associated with SAPS.

1. Band-resisted internal and external rotation: from a standing position with the arm fully adducted at the side and the elbow at 90° of flexion, the patient pulls a resistance band at waist height either toward the body (internal rotation) or away from the body (external rotation)
2. Weight-resisted internal and external rotation: from a sidelying position with the arm fully adducted at the side and the elbow at 90° of flexion, the patient lifts a weighted dumbbell against gravity either toward the body (internal rotation) or away from the body (external rotation)
3. Scaption: from a standing position with the arm 30° forward of the frontal plane and the thumb either up or down, the patient lifts the upper extremity against gravity in a pain-free range. This exercise can be performed with or without added weight
4. Seated chair press: from a seated position with the back straight, the patient pushes down on the chair, thereby lifting the body upward
5. Spine flexion/extension: from a quadruped position with the knees under the hips and the hands under the shoulders, the patient arches the back and pulls the neck forward into flexion. The patient then drops the belly toward the floor and extends the neck
6. Press-up: from a supine position, the patient locks the elbow and maintains 90° of shoulder flexion while holding a weighted dumbbell. The patient then protracts the shoulder to lift the dumbbell toward the ceiling
7. Upright row: from a supported position in standing, the patient bends forward and holds a weighted dumbbell. The patient then lifts the dumbbell toward the side of the body by flexing the elbow, pulling the shoulder blade back, and retracting the shoulder
8. Rows: from a seated or standing position, the patient abducts the shoulders to 90° while flexing and internally rotating the shoulders. The patient then pulls a resisted band by flexing the elbows, pulling the scapulae together, and retracting the shoulders
9. Low rows: from a standing or prone position, the patient keeps the elbows extended and pulls a resisted band into shoulder extension

IFC Parameters

A total of 2 channels (ie, 4 topical, 50 × 50-mm self-adhesive pads) were placed around the area of pain (ie, the subacromial space) and set to an amplitude-modulated frequency of 15 to 120 Hz and an intensity rated by the patient as "strong but comfortable tingling" for 20 minutes, equal to that of the electrical dry needling treatment.

Abbreviations: IFC, interferential current; NTMEX, nonthrust peripheral joint/soft tissue mobilization, exercise, and interferential current; SAPS, subacromial pain syndrome.

APPENDIX C

SELF-REPORT OUTCOME MEASURES

Outcome Measure	Description and Psychometric Properties
SPADI[55]	A 5-item subscale that measures pain and an 8-item subscale that measures disability (scored 0-10), where 0 represents no pain/no difficulty and 10 represents the worst pain imaginable/so difficult that it requires help. Each subscale is summed and transformed to a percentage score out of 100. The mean is taken of the 2 subscales to give a total SPADI score out of 100 (higher scores mean greater impairment or disability). The SPADI has been found to possess excellent reliability, validity, and responsiveness. The MCID for the SPADI has been found to be 10 points; however, changes between 8 and 13 points in the SPADI score should be considered clinically meaningful
NPRS[62]	11-point scale ranging from 0 ("no pain") to 10 ("worst pain imaginable"). The NPRS is a reliable and valid instrument to assess pain intensity. The MCID for the NPRS has been shown to be between 1.1 and 2.17 points in patients with shoulder pain, which is consistent with the findings in heterogeneous groups of patients with musculoskeletal pain conditions
Global rating of change scale[40]	15-point scale ranging from –7 (a very great deal worse) to 0 (about the same) to +7 (a very great deal better). Scores of +4 and +5 have typically been indicative of moderate changes in patient status. In this study, +5 or greater was used as the cutoff score to define clinically important self-perceived improvement
Medication intake	Measured as the number of times the patient had taken prescription or over-the-counter analgesic or anti-inflammatory medication in the past week for shoulder pain, with 5 options: (1) not at all, (2) once a week, (3) once every couple of days, (4) once or twice a day, or (5) 3 or more times a day

Abbreviations: MCID, minimal clinically important difference; NPRS, numeric pain-rating scale; SPADI, Shoulder Pain and Disability Index.