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Acupuncture Treatment of Adhesive Capsulitis of the Shoulder: A Randomized Controlled Pilot Trial

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ABSTRACT

Background: Adhesive capsulitis (AC) is a common condition that includes shoulder pain and limited movement. Despite more than 100 years of AC treatment, the most efficacious treatment remains unclear. The aim of this study was to evaluate the feasibility of a randomized controlled trial (RCT) using acupuncture for AC.
Methods: Thirty participants with AC were randomly assigned to acupuncture (A) or sham acupuncture (SA) groups. The participants received 15 acupuncture sessions over 6 weeks, and follow-up occurred for an additional 4 weeks thereafter. The primary clinical outcome was the numeric rating scale (NRS) for shoulder pain 6 weeks from the baseline. Secondary outcomes included range of motion (ROM) in the shoulder, the shoulder pain and disability index (SPADI), the EuroQol-5 dimensions (EQ-5D), the Pittsburgh sleep quality index (PSQI), and the patient global impression of change (PGIC).
Results: Thirty participants were enrolled out of 37 screened individuals. Recruitment was conducted between August 2014 until May 2015. A total of 28 participants (93%) completed the 6-week intervention, and 26 participants (87%) completed the study. NRS, ROM, SPADI, EQ-5D, PSQI, and PGIC scores improved in both the experimental group and the sham group after 6 weeks, but the difference between the groups was not statistically significant. Adverse events were reported by 12 participants, although these events were not associated with acupuncture.
Conclusion: A future RCT for AC may be feasible with some modifications to the recruitment plan and the secondary outcome measurement methods.

Introduction

Adhesive capsulitis (AC) is a common condition that causes shoulder pain and limited movement [1], and occurs in 3% to 5% of the general population [2]. Despite more than 100 years of AC treatment, the definition, diagnosis, pathology, and treatment options remain unclear [3]. The goals of AC treatment include relieving pain, restoring movement, and regaining shoulder function [1]. Western medical treatments for AC include physiotherapy, hydrodilatation, manipulation under anesthesia, arthroscopic capsular release, and steroid administration [3]. In contrast, Eastern medical treatments for AC include techniques such as acupuncture, herbal medication, moxibustion, and cupping [4].

Acupuncture is frequently used to treat various shoulder problems [5]. Furthermore, a previous review indicated that acupuncture may be helpful for treating shoulder pain however, this study also suggested that further studies are required before it can be recommended as a treatment for AC [6]. Another review of randomized controlled trials (RCTs) of acupuncture for shoulder pain found that 11 out of 16 RCTs demonstrated significant differences between the acupuncture and control (physiotherapy,

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surface needling, etc.) groups. Moreover, 3 out of 16 RCTs used non-penetrating sham controls, and AC was not the target condition in 1 of 3 RCTs [7]. Hence, the efficacy of acupuncture on AC was not accurately assessed.

Considering this, a randomized controlled pilot trial was designed to assess the feasibility of a RCT using acupuncture for AC.

Materials and Methods

Trial design

This study was a 2-arm, randomized, controlled, and parallel-designed pilot trial. The study period was 10 weeks, which included a 6-week intervention procedure and a 4-week follow-up examination. The trial design is shown as a flow diagram in Fig. 1.

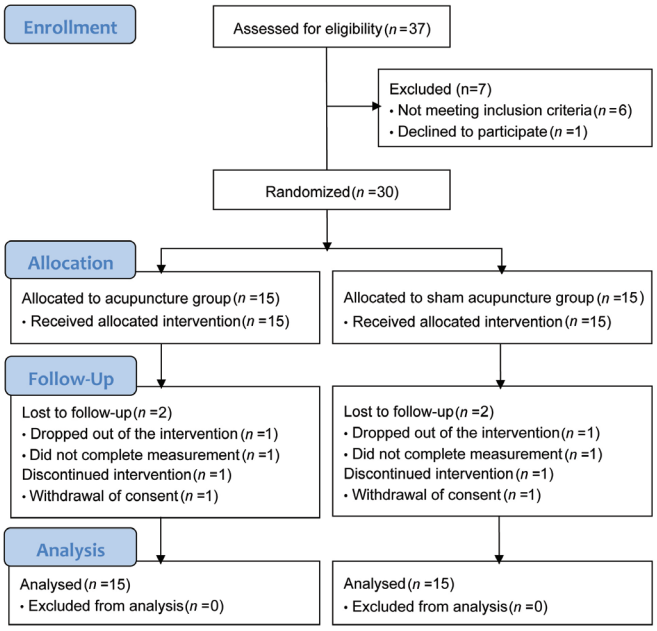

Fig. 1. Trial flow chart.

Participants

Participants were recruited from Daejeon Oriental Hospital of Daejeon University, Daejeon, Korea. When a participant contacted the clinical trial center by telephone or by e-mail through the recruitment advertisement, the clinical research coordinator scheduled the participant's visit to the clinical trial center. When the participant visited, the clinical research coordinator gave the participant a screening number. The researcher then provided the participant with sufficient information about this study and received written consent. After that, the participant was evaluated for eligibility criteria of the study.

Inclusion criteria

Inclusion criteria were as follows: (1) men and women aged 19 to 65 years, (2) patients who had experienced chronic shoulder pain in either 1 or both shoulders for a period of 3 to 12 months, (3) patients who experienced shoulder pain and had weekly numeric rating scale (NRS) scores of ≥ 4 during a screening examination, and (4) providing written informed consent.

Exclusion criteria

Exclusion criteria were as follows: (1) diagnosis of cervical radiculopathy or treatment for cervical radiculopathy within the previous 3 months, (2) injured shoulder or shoulder surgery, (3) diagnosis of another pathological condition by clinical or radiological shoulder examination, such as rotator cuff injury, shoulder impingement syndrome, rheumatoid arthritis, or osteoarthritis, (4) use of adrenal cortex hormone or steroids for another medical condition, (5) the patient received another treatment for shoulder pain in the 2 weeks prior to screening, such as medications, various Eastern medicine treatments, injections, or physical therapy, (6) hypersensitivity to acupuncture, (7) the patient was pregnant, breastfeeding, or planning to become pregnant during the duration of the trial period, (8) psychoneurotic disorders including epilepsy, depression, or panic disorder, (9) surgery or other treatments for shoulder pain during the study, and (10) the investigator considered the individual unsuitable for the clinical trial (e.g. considered to be unable to cooperate in the research process such as questionnaire response due to difficult communication).

Ethical considerations

This study was approved by the institutional review board of the Daejeon Oriental Hospital of Daejeon University (djomc-120). The study was registered at the Clinical Research Information Service (KCT0001471). All participants provided written informed consent. The information included the purpose of the study, participation period, number of participants, study procedure, benefits from participation, anticipated harms, withdrawal of consent to participation, rules to follow during the study period, compensation and treatment in case of damage related to research, confidentiality of personal information, reasons for participation being discontinued during the study, and the name and contact information of the researcher. All care was taken to protect the privacy of participants.

Sample size

The sample size was determined by the recommended minimum number per group for pilot studies (12 participants) [8]. A predicted 20% dropout rate necessitated 15 participants per group (30 participants for the study).

Randomization

Participants were randomly assigned to acupuncture (A) or sham acupuncture (SA) groups, with equal numbers in each group. An independent statistician generated the randomization sequence using a computer program (Strategic Applications Software (SAS), version 9.1.3; SAS Institute Inc., Cary, NC, USA). Blocked randomization with randomized block size was applied.

Allocation concealment

Each generated randomization sequence was sealed in sequentially numbered, opaque envelopes. The researcher opened the envelopes in sequential order as each participant met all eligibility criteria. Opened envelopes were stored in a double-locked cabinet.

Blinding

Participants and outcome assessors remained blind to group assignments until study completion.

Interventions

Participants in both groups received 15 intervention sessions for 6 weeks. In the A group, treatment points were LI10 (Susamni), LI15 (Gyeonu), LI16 (Geogol), LU2 (Unmun), LU5 (Cheoktaek), SI9 (Gyeonjeong), SI11 (Cheonjong), TE14 (Gyeollyo), TE15 (Cheollyo), and SP19 (Hyunghyang) on the affected side. The acupoints were chosen based on the theory of meridians in traditional Oriental medicine [7,9,10]. After inducing a *de qi* sensation, the needles were retained for 20 minutes [7]. In the SA group, non-penetrating Park sham placebo devices were used [11]. The treatment points were LI16, SI9, SI11, TE14, TE15, BL12 (Pungmun), BL13 (Pyesu), BL14 (Gworeumsu), BL15 (Simsu), and BL16 (Doksu) on the affected side [7,9,10]. To maintain blinding, acupuncture points in the back (BL12, BL13, BL14, BL15, and BL16) were used instead of LI10, LI15, LU2, LU5, and SP19, which were visible to participants during the procedure. The devices remained in position for 20 minutes without inducing a *de qi* sensation [7]. During the study period, medications and Oriental medicine treatments for AC were not allowed, but self-initiated exercise and the usual management for AC were allowed. Detailed information on interventions are shown in Appendix 1.

Outcomes

NRS

The primary clinical outcome was the NRS score for shoulder pain at Week 7. The NRS consisted of a horizontal straight line with a numerical scale ranging from 0 to 10. The far-left side of the scale (0) corresponded to "no pain," while "worst pain ever experienced" (10) was represented at the far-right end of the scale [12]. Participants were asked to select a number that corresponded to their average shoulder pain over the past week. The NRS scores measured at weeks 4 and 11 were secondary outcomes.

Shoulder range of motion

A digital goniometer (iGaging, San Clemente, CA, USA) was used to assess range of motion (ROM) in the shoulder joint, using flexion, abduction, internal rotation, and external rotation movements. To reduce measurement errors, prior to the start of the study, the ROM measurers were trained via a one-day course. The measurements were always performed in the same order (flexion, abduction, internal rotation, and external rotation). The ROM was measured at baseline, Week 4, Week 7, and Week 11.

Shoulder pain and disability index

The shoulder pain and disability index (SPADI) comprised the pain (5 items) and disability (8 items) subscales. Each item was scored on an 11-point scale. The SPADI total score was calculated by averaging the 2 subscale scores [13]. The SPADI was measured at baseline, Week 7, and Week 11.

EuroQol-5 dimensions

Quality of life was measured using the EuroQol-5 dimensions (EQ-5D). The EQ-5D descriptive system was a standardized tool for measuring health-related quality of life and consists of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) [14]. The EQ-5D was measured at baseline, Week 7, and Week 11.

Pittsburgh sleep quality index

The Pittsburgh sleep quality index (PSQI) assessed sleep quality and identified sleep disturbances [15]. Seven items, including subjective sleep quality, sleep latency, sleep time, habitual sleep efficiency, sleep disturbance, sleeping pills, and daytime dysfunction, were measured at baseline, Week 7, and Week 11.

Patient global impression of change

The patient global impression of change (PGIC) assessed the degree of improvement experienced by participants following treatment. Participants were asked how much their shoulder pain improved compared to before the study and were asked to choose 1 of the following 7 answers: "very much improved," "much improved," "minimally improved," "no change," "minimally worse," "much worse," or "very much worse" [16]. The PGIC was measured at Weeks 7 and 11.

Blind test

Participants were asked to guess which treatment they received, by choosing 1 of the following 3 answers: "classical acupuncture," "non-classical acupuncture," or "don't know." The blind test was conducted after the first and last study sessions.

Harms

All adverse events (AEs) were recorded by practitioners, using an AE report form. The following data were recorded: the date of occurrence and disappearance, severity and outcomes of AEs, measures taken in relation to the study and their relationships with the treatment, medicines or treatments other than the study treatment, and details of any treatment for AEs. The severity of AEs was classified into 3 grades (1 = mild, 2 = moderate, and 3 = severe). The relationship between acupuncture and AEs was classified into 6 categories (1 = definitely related, 2 = probably related, 3 = possibly related, 4 = probably not related, 5 = definitely not related, and 6 = unknown).

Statistical analyses

Between-group comparisons were analyzed using analysis of covariance (ANCOVA) with the evaluation values of each outcome as a dependent variable, baseline value as a covariate, and group as a fixed factor. The analysis was performed with an α-value of 0.05 and power of 0.80. Additionally, a repeated measures analysis of variance (RM ANOVA) was performed to assess a potential interaction between timepoint and group. Other outcomes (ROM, SPADI, EQ-5D, and PSQI) were similarly analyzed. PGIC was analyzed using analysis of variance (ANOVA), since PGIC had no baseline value and was not included in the RM ANOVA. The blind test was analyzed using a Fisher's exact test. Within-group comparisons were analyzed with either paired *t* test or Wilcoxon signed-rank test. For sociodemographic characteristics, numeric variables were presented as means and standard deviations, while categorical variables were presented as frequencies and percentages. Analyses were conducted on both a full analysis set (FAS) and a per-protocol set (PPS). A FAS was used to describe the set that was as complete as possible and as close as possible to the intention-to-treat (ITT) ideal of including all randomized participants. The PPS included participants who were most compliant with the study protocol [17]. The main analyses were conducted on the FAS. Missing data were imputed by multiple imputation. Statistical analyses were performed using the SAS program (version 9.4; SAS Institute Inc., Cary, NC, USA).

Table 1. Baseline Characteristics for Each Group.

Variable	Experimental group acupuncture (n = 15)	Sham group acupuncture (n = 15)
Gender (men/ women)	9 (60) / 6 (40)	9 (60) / 6 (40)
Age (y)	55.67 ± 4.64	51.53 ± 10.17
Body mass index	24.66 ± 2.69	24.00 ± 2.58
Exercise	10 (66.67)	12 (80)
Alcohol consumption	11 (73.33)	6 (40)
Previous treatment for adhesive capsulitis		
Medication	3 (20)	6 (40)
Injection	4 (26.67)	8 (53.33)
Physical therapy	1 (6.67)	1 (6.67)
Eastern medicine	2 (13.33)	3 (20)
Self-initiated exercise	0 (0)	1 (6.67)

Data are presented as mean ± SD or n (%), where appropriate.

Table 2. Outcomes of Numeric Rating Scale.

Wk	A group	SA group	p	p	p	LSMD [95% CI]
	Mean (SD)	Mean (SD)	(within A group)†	(within SA group)†	(between groups)§	
Baseline	6.00 (1.31)	6.00 (1.41)	-	-	-	-
Wk 4	4.47 (1.36)	4.50 (1.83)	0.0105*‡	0.0005*	0.9654	0.02 [-1.07, 1.11]
Wk 7	3.43 (1.60)	3.14 (2.54)	0.0021*	0.0003*	0.7345	-0.27 [-1.83, 1.29]
Wk 11	4.08 (2.02)	3.00 (2.77)	0.0297*	0.0011*	0.3250	-1.00 [-3.00, 1.00]

A, acupuncture; CI, confidence interval; LSMD, least squares mean difference; SA, sham acupuncture.
* $p < 0.05$.
† Paired t test.
‡ Wilcoxon signed-rank test.
§ Analysis of covariance.

Results

Recruitment and feasibility

Recruitment was conducted from August 2014 to May 2015. Thirty participants were selected from 37 screened individuals (Fig. 1). In the A group, 218 acupuncture sessions (97%) were administered during the study period. In the SA group, 211 acupuncture sessions (94%) were administered during the study period. A total of 28 participants (93%) completed the 6-week intervention. A total of 4 participants (13%) dropped out or were lost to follow-up (Fig. 1). The reasons for the drop-out were withdrawal of consent (n = 2: 1 in the A group, due to work shift; the other in the SA group, not enough time) and the use of prohibited concomitant treatments on the shoulder during the study period (n = 2: 1 in the A group, injection therapy; the other in the SA group, acupuncture and moxibustion treatment).

Baseline characteristics

The sociodemographic and clinical characteristics of the participants are given in Table 1. No significant differences were observed between the groups regarding gender, age, body mass index, exercise, alcohol consumption, and medical treatments for AC.

Clinical outcomes

No significant differences occurred between the 2 groups for NRS, ROM (Weeks 4, 7, and 11), EQ-5D, SPADI, or PSQI (Weeks 7 and 11) scores. In the A group, significant improvements occurred on the NRS (Weeks 4, 7, and 11), EQ-5D (Week 11), SPADI (pain, disability, and total, at both Weeks 7 and 11), and PSQI (Week 11) compared to baseline. In the SA group, significant improvements occurred on the NRS (Weeks 4, 7, and 11), ROM (flexion at Week 11; abduction at Weeks 4, 7, and 11; and external rotation at Week 7), EQ-5D (Week 11), SPADI (pain and total, at Weeks 7 and 11; disability at Week 7), and PSQI (Week 11) compared to baseline (Tables 2–5).

There was no interaction between timepoint and group on the NRS (p = 0.4106), ROM (flexion, p = 0.3343; internal rotation, p = 0.4634; external rotation p = 0.5667), SPADI (pain, p = 0.5168; disability, p = 0.7545; total, p = 0.9456), EQ-5D (p = 0.4826), or PSQI (p = 0.9926). The only significant difference was for ROM of shoulder abduction (p = 0.0308). No significant differences occurred between the 2 groups for PGIC scores (Week 7, p = 0.8674; Week 11, p = 0.8702). At Week 7, 12 of 14 participants in the A group (86%) answered that they improved (minimally improved, n = 4; much improved, n = 5; very much improved, n = 3); 11 of 14 participants in the SA group (79%) reported that they improved (minimally improved, n = 2; much improved,

Table 3. Outcomes of Range of Motion.

Motion	Wk	A group	SA group	*p* (within A group)†	*p* (within SA group)†	*p* (between groups)§	LSMD [95% CI]
		Mean (SD)	Mean (SD)				
Flexion	Baseline	142.43 (17.81)	125.66 (16.44)	-	-	-	-
	Wk 4	142.53 (14.64)	124.41 (20.23)	0.9778	0.5016‡	0.3283	-6.06 [-18.24, 6.11]
	Wk 7	145.40 (21.63)	133.36 (20.01)	0.3234	0.0808‡	0.8711	1.14 [-12.67, 14.95]
	Wk 11	142.89 (25.68)	138.46 (24.75)	0.8064	0.0315*‡	0.6144	5.91 [-17.15, 28.98]
Abduction	Baseline	121.89 (27.67)	103.36 (22.76)	-	-	-	-
	Wk 4	117.38 (28.72)	114.48 (25.29)	0.5647	0.0032*	0.1492	14.69 [-5.29, 34.66]
	Wk 7	128.20 (29.61)	116.47 (22.60)	0.2307	0.0204*	0.7354	-3.63 [-24.78, 17.52]
	Wk 11	126.12 (30.46)	126.83 (22.97)	0.5172	0.0014*	0.2154	14.67 [-8.57, 37.92]
Internal rotation	Baseline	57.61 (10.46)	65.23 (13.59)	-	-	-	-
	Wk 4	57.02 (9.77)	63.14 (13.07)	0.8210	0.5269	0.6620	1.77 [-6.17, 9.70]
	Wk 7	59.21 (13.82)	67.78 (12.34)	0.4442	0.4632	0.6945	1.80 [-7.20, 10.81]
	Wk 11	65.28 (12.99)	64.84 (13.73)	0.0737	0.8006	0.5350	-3.69 [-15.35, 7.97]
External rotation	Baseline	54.45 (15.07)	51.04 (18.48)	-	-	-	-
	Wk 4	60.29 (15.63)	52.56 (14.03)	0.0647	0.1990	0.5093	-2.88 [-11.45, 5.70]
	Wk 7	60.21 (12.58)	59.52 (15.57)	0.2277	0.0048*	0.6793	1.97 [-7.38, 11.32]
	Wk 11	52.89 (13.52)	51.22 (14.66)	0.6571	0.5776	0.6310	2.72 [-8.41, 13.85]

A, acupuncture; CI, confidence interval; LSMD, least squares mean difference; SA, sham acupuncture.
* $p < 0.05$.
† Paired t test.
‡ Wilcoxon signed-rank test.
§ Analysis of covariance.

Table 4. Outcomes of Shoulder Pain and Disability Index.

SPADI	Wk	A group	SA group	*p* (within A group)†	*p* (within SA group)†	*p* (between groups)§	LSMD [95% CI]
		Mean (SD)	Mean (SD)				
Pain	Baseline	61.87 (14.94)	64.27 (19.27)	-	-	-	-
	Wk 7	39.29 (14.24)	40.71 (25.67)	0.0014*	0.0011*	0.7077	-2.94 [-18.33, 12.45]
	Wk 11	38.62 (21.01)	35.69 (30.67)	0.0038*	0.0005*	0.4298	-7.41 [-25.81, 10.99]
Disability	Baseline	46.52 (20.21)	40.36 (22.54)	-	-	-	-
	Wk 7	25.91 (17.39)	26.38 (21.63)	0.0026*	0.0216*	0.9999	0.00 [-15.03, 15.03]
	Wk 11	27.62 (20.04)	28.49 (27.72)	0.0086*	0.1211	0.9818	-0.21 [-17.93, 17.51]
Total	Baseline	52.39 (16.95)	49.54 (20.41)	-	-	-	-
	Wk 7	31.04 (15.59)	31.87 (22.15)	0.0010*	0.0053*	0.9121	-0.81 [-15.24, 13.62]
	Wk 11	31.84 (20.08)	31.24 (28.44)	0.0040*	0.0181*	0.7995	-2.28 [-19.24, 15.29]

A, acupuncture; CI, confidence interval; LSMD, least squares mean difference; SA, sham acupuncture; SPADI, shoulder pain and disability index.
* $p < 0.05$.
† Paired *t* test.
‡ Wilcoxon signed-rank test.
§ Analysis of covariance.

Table 5. Outcomes of Euroqol-5 Dimensions and Pittsburgh Sleep Quality Index.

Outcome	Wk	A group	SA group	*p* (within A group)†	*p* (within SA group)†	*p* (between groups)§	LSMD [95% CI]
		Mean (SD)	Mean (SD)				
EQ-5D	Baseline	0.80 (0.13)	0.80 (0.11)	-	-	-	-
	Wk 7	0.88 (0.04)	0.84 (0.12)	0.0547‡	0.1279‡	0.2296	-0.04 [-0.10, 0.02]
	Wk 11	0.88 (0.05)	0.87 (0.10)	0.0234*‡	0.0078*‡	0.7822	-0.01 [-0.06, 0.04]
PSQI	Baseline	9.93 (2.70)	8.40 (2.34)	-	-	-	-
	Wk 7	8.91 (2.28)	7.46 (2.03)	0.1992	0.0511	0.3089	-0.81 [-2.38, 0.75]
	Wk 11	8.18 (2.60)	6.75 (2.13)	0.0076*	0.0307*	0.3726	-0.78 [-2.51, 0.94]

A, acupuncture; CI, confidence interval; EQ-5D, Euroqol-5 dimensions; LSMD, least squares mean difference; PSQI, Pittsburgh sleep quality index; SA, sham acupuncture.
* $p < 0.05$.
† Paired *t* test.
‡ Wilcoxon signed-rank test.
§ Analysis of covariance.

Table 6. Adverse Events.

Symptom	No. of patients & group	Start & End date		Intensity	Causal relation ship	Action related to intervention	Treatment	Outcome
URI	5 Sham	11/22/14	11/24/14	Mild	No	No	Medication	Improved
	Sham	12/02/14	12/05/14	Mild	No	No	Medication	Resolved
	Expt	12/22/14	12/24/14	Mild	No	No	Medication	Resolved
	Sham	12/27/14	12/30/14	Mild	No	No	Medication	Resolved
	Sham	01/03/15	01/04/15	Moderate	No	No	Medication	Resolved
Headache	2 Sham	10/19/14	10/19/14	Mild	No	No	Medication	Resolved
	Sham	11/23/14	11/23/14	Mild	No	No	Medication	Resolved
Gastritis	2 Expt	12/16/14	12/18/14	Mild	No	No	Medication	Resolved
	Sham	02/03/15	03/02/15	Mild	No	No	Medication	Resolved
Toothache	1 Expt	11/19/14	11/20/14	Mild	No	No	Medication	Resolved
Shoulder pain	1 Sham	01/12/15	Unknown	Moderate	No	Stopped	Non-drug treatment	Improved
Lower back pain	1 Sham	01/09/15	02/04/15	Moderate	No	No	Medication	Improved

Expt, Experimental; URI, upper respiratory infection.

n = 6; very much improved, *n* = 3). At Week 11, 11 of 13 participants in the A group (85%) answered that they improved (minimally improved, *n* = 3; much improved, *n* = 5; very much improved, *n* = 3); 11 of 13 participants in the SA group (85%) reported that they improved (minimally improved, *n* = 2; much improved, *n* = 6; and very much improved, *n* = 3).

In the blind test, 6 of 15 participants in the A group (40%) guessed that they belonged to the A group, 1 participant (7%) guessed that he belonged to the SA group, and 8 participants answered "don't know" (53%) after the first intervention. In the SA group, 7 of 15 participants (47%) guessed that they belonged to the A group, 4 participants (27%) guessed that they belonged to the SA group, and 4 participants answered "don't know" (27%) after the first intervention. After the last intervention, 9 of 14 participants in the A group (64%) guessed that they belonged to the A group, 1 participant (7%) guessed that they belonged to the SA group, and 4 participants answered "don't know" (29%). In the SA group, 9 of 14 participants (64%) guessed that they belonged to the A group, 2 participants (14%) guessed that they belonged to the SA group, and 3 participants answered "don't know" (21%) after the last intervention. No significant differences occurred between the 2 groups on the blind test (after first session, $p = 0.2425$; after last session, $p = 0.9999$).

Harms

AEs were reported by 12 participants; however, they were judged to have no causal relationship with the study treatments (Table 6).

Discussion

The feasibility of a RCT was evaluated using acupuncture for AC treatment. Research procedures (e.g., screening, randomization, intervention, and questionnaire responses) worked well overall. More than 90% of the participants completed the 6-week intervention. AEs occurred for 12 participants (40%) (3 in the A group and 9 in the SA group), but these events were not associated with the study treatments. Recruiting began in mid-August 2014 and ended at the end of May 2015, making the average recruitment rate approximately 3 patients per month. In future studies, improvements in the recruitment rate would be desirable.

Among the clinical outcomes, SPADI, ROM, EQ-5D, and PSQI were chosen considering the most frequently addressed concepts using the international classification of functioning, disability and health (ICF) in measures of shoulder pain [18]. On the other hand, NRS and PGIC were chosen considering 2 of the core chronic pain outcome domains (pain intensity and participant ratings of overall improvement) recommended by the initiative on methods, measurement, and pain assessment in clinical trials (IMMPACT) [19].

In a previously reported meta-analysis of sham-controlled randomized clinical trials, 5 trials with a total of 495 participants compared mean shoulder pain scores between the A and SA groups. The standardized mean difference was -0.63 (range = -0.91 to -0.36, $p < 0.001$), indicating that there was a moderate effect of the A group compared to the SA group [20]. The effects of the A group may have been masked by differences in design (such as target disease, intervention, and control device) between studies included in the meta-analysis and the present study. Insufficient power to detect differences in efficacy between groups would also explain discrepancies in the results. In addition, improvement responders were considered (not initially planned) at the following 2 levels: 30% responder (≥ 30% reduction from baseline NRS) and 50% responder (≥ 50% reduction from baseline NRS). Reporting outcomes as the percentage of patients responding or achieving a low pain state is preferable to the average changes in pain intensity because the population distribution of pain intensity tends not to be bell-shaped [21]. In the present study, the 30% responder after 6 weeks of intervention was 10 in each of the A and SA groups (66.7%). The 50% responder after 6 weeks of intervention was 9 in each of the A and SA groups (60%). In future studies, it may be necessary to reexamine the results obtained by including responder outcomes in the evaluation variables.

For the within-group comparison, the change from baseline NRS scores was -2.57 (an improvement of 42.8%) in the A group, and -2.86 (improvement of 47.7%) in the SA group after 6 weeks. A RCT for chronic shoulder pain conducted in 2007, found changes from baseline of -2.5 (improvement of 50%) in the A group, and -0.7 (improvement of 16.3%) in the SA group after 10 treatments over 5 weeks [22]. A reduction from baseline of 2 points (approximately 30%) in pain intensity on the NRS represents a clinically important difference [16]. In the present study, change from baseline in SPADI total scores was -21.35 (improvement of 40.8%) in the A group, and -17.67 (improvement of 35.7%) in the SA group after 6 weeks. A RCT for chronic shoulder pain conducted in 2009 found that the change from baseline SPADI total scores was -20.4 in the A group, and -6.5 in the SA group after 12 treatments over 6 weeks (baseline SPADI values not presented) [23]. When a patient is tested and then retested, a change of 18 points represents the minimum difference in the SPADI total score required to state (with 95% confidence), that a real change is responsible for the difference, rather than measurement error (i.e., 18 is the minimum score indicating change) [24].

In the present study, changes in the NRS and SPADI scores of the A group demonstrated a clinically significant improvement similar to previously reported effects; however, the SA group scores indicated more improvement than those reported previously. In a validity study of SPADI conducted in 2012, SPADI had a significant correlation with NRS (correlation coefficient = 0.946) and ROM (correlation coefficient = -0.927) at $p < 0.01$ level [13]. In this study, NRS and SPADI scores before and after intervention tended to change in the same direction in both groups. However, the results of ROM measurement in the A group showed no significant change after the intervention, which was not consistent with the result of the previous study [13]. The ROM measurers and the acupuncture practitioners each received 1-day study-related education before the study initiation, but while the practitioners were already very familiar with acupuncture treatment, the ROM measurers were the first to measure the ROM, so the measurement error between the ROM measurers might be relatively larger than the intervention error between the practitioners. This might have affected the ROM measurement results of this study, leading to differences compared with those from the previous study [13]. It was reported that patients with AC had significant incidence of sleep disturbance and had a significantly lower quality of life [25]. In this study, PSQI and EQ-5D tended to change in the opposite direction before and after intervention in accordance with the result of the previous study [25].

To evaluate the success of blinding, index values were calculated (not initially planned) using the blinding index (BI) that was reported in 2004 [26]. After the first intervention, the BI value of the A group was 0.33 (95% confidence interval, 0.03 to 0.64), and the BI value of the SA group was -0.20 (-0.62 to 0.22). After the last intervention, the BI value of the A group was 0.57 (0.25 to 0.90) and the value of the SA group was -0.50 (-0.88 to -0.12). It was reported that "random guess" and "wishful thinking" (e.g., participants tend to believe that they received treatment) are the most ideal blinding scenarios for incurring minimal bias [27]. Using a 0.2 BI threshold value [28], the results of the BI calculation in this study after the last intervention were close to "wishful thinking." This may partly explain the unexpected excellent improvements for the SA group.

This study has the following strengths and weaknesses. In terms of strengths, this study achieved high compliance with the intervention and confirmed the safety of acupuncture for AC. However, in terms of limitations, SA appears to have some physiological effects and may not be a perfect placebo. In a systematic review of 61 clinical trials comparing the efficacy of SA with other placebos, it was suggested that SA interventions might be associated with greater efficacy than pharmacological or other physical placebos [29]. Second, some unmeasured factors, such as self-initiated exercise and expectation of the treatment, may have affected the outcomes. Self-initiated exercise for AC was not prohibited during the study period, and data was not collected on whether the exercise was performed or how much participants in each group may have exercised. Participants' expectations of acupuncture were also not investigated. In future studies, these factors should be measured, and sensitivity analyses that take these factors into account should be performed.

Conclusions

The results from this study suggest that a future RCT for AC may be possible, with some modifications to the recruitment plan and the secondary outcome measurement methods.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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Appendix 1.

Checklist for Items in STRICTA (Standards for Reporting Interventions in Controlled Trials of Acupuncture).

Item	Detail	Description
1. Acupuncture rationale	1a) Style of acupuncture	Manual acupuncture.
	1b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate	Textbook of acupuncture medicine, journal papers (7, 9, and 10 of the manuscript references), and consensus of Korean medicine specialists.
	1c) Extent to which treatment was varied	Standardized treatment (if necessary, additional use of two Ashi points was allowed).
2. Details of needling	2a) Number of needle insertions per subject per session	Maximum of 12 insertions per subject, per session (10 to 12 insertions).
	2b) Names (or location if no standard name) of points used (uni/bilateral)	Names of points used were LI10, LI15, LI16, LU2, LU5, SI9, SI11, TE14, TE15, and SP19 on the affected side. As needed, two Ashi points were added.
	2c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level	Between 0.3 and 1 cun.
	2d) Response sought (e.g. de qi or muscle twitch response)	De qi response.
	2e) Needle stimulation	Manual stimulation (twirling or lifting-thrusting methods).
	2f) Needle retention time	20 minutes.
	2g) Needle type (diameter, length, and manufacturer or material)	Stainless steel disposable needles (0.25-mm diameter, 40-mm length; Dongbang Acupuncture Inc., Korea).
3. Treatment regimen	3a) Number of treatment sessions	Participants received 15 intervention sessions for 6 weeks (average three times per week for the first three weeks, then average two times per week for the next three weeks).
	3b) Frequency and duration of treatment sessions	
4. Other components of treatment	4a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)	Participants were prohibited from using concomitant treatments that could directly affect the outcomes of the study.
	4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients	Acupuncture was provided in an environment similar to an actual acupuncture clinic. Participants were informed that they would receive classical acupuncture or non-classical acupuncture and that the beneficial effects of both types of acupuncture were not known.
5. Practitioner background	5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)	Acupuncture was performed by a total of four practitioners (one male and three females). They obtained the Korean medicine doctor's license with six years of college education and the qualification as a specialist of Korean medicine with four years of clinical training. Practitioners attended a one-day training program, including patient screening, acupuncture, and evaluation methods necessary for carrying out the study.
6. Control or comparator interventions	6a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice	A clinical trial of acupuncture treatment for frozen shoulder. J Korean Acupunct Moxib Soc. 2006;23:165–177. Validating a new non-penetrating sham acupuncture device: two randomised controlled trials. Acupunct Med. 2002;20:168–174.
	6b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above.	Participants received 15 intervention sessions for 6 weeks (average three times per week for the first three weeks, then average two times per week for the next three weeks). Names of points used were LI16, SI9, SI11, TE14, TE15, BL12, BL13, BL14, BL15, and BL16 on the affected side (10 insertions per session). The Park sham devices remained in position for 20 minutes without inducing a de qi sensation. Participants were prohibited from using concomitant treatments that could directly affect the outcomes of the study.

Note: This checklist is designed to replace CONSORT (consolidated standards of reporting trials) 2010's item 5 when reporting an acupuncture trial.