Integrative Medicine Research 10 (2021) 100693

Contents lists available at ScienceDirect

Integrative Medicine Research

journal homepage: www.elsevier.com/locate/imr

Original Article

Effectiveness and safety of fluoroscopy-guided acupuncture for subacromial impingement syndrome: A randomized, patient-assessor blind, parallel clinical trial

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ARTICLE INFO

Article history:
Received 26 June 2020
Revised 27 October 2020
Accepted 30 October 2020
Available online 18 November 2020

Keywords:
Subacromial impingement syndrome
Randomized clinical trials
Acupuncture
Fluoroscopy guide

ABSTRACT

Background: Subacromial impingement syndrome (SIS) is one of the most common causes of shoulder pain, and acupuncture treatment is widely used as treatment. However, no studies have examined image-guided acupuncture for SIS. This study evaluated the effectiveness and safety of low-dose X-ray guided acupuncture (LA) in patients with SIS.

Methods: A total of 54 patients with SIS were randomly allocated to the LA group and the conventional acupuncture (CA) group. Two acupuncture treatment sessions were conducted for a week, and follow up was conducted after three weeks. The primary outcome was pain intensity measured by the visual analogue scale (VAS) during the Neer and Hawkins test. The incidence rate of shoulder impingement sign, the modified Constant-Murley score (CMS) and the Shoulder Pain and Disability Index (SPADI) were assessed as other outcomes. All indicators were assessed at baseline and after one week and three weeks. For safety evaluation, adverse events were monitored in both groups.

Results: The change in pain during the Neer test after one week from baseline was more significant in the LA group than in the CA group (p=0.008). However, the Hawkins test did not show a difference between the two groups. The incidence rate of shoulder impingement sign and the changes in CMS and SPADI were not significantly different between the two groups at one week, but after three weeks, SPADI was more significantly improved in the LA group (p=0.024). No adverse events were related to this trial.

Conclusion: LA was more effective than CA in relieving pain and improving function in terms of VAS and SPADI.

Trial registration: This study was registered on 23 March 2018 at the Clinical Research Information Service: KCT0002751.

1. Introduction

Subacromial impingement syndrome (SIS) is one of the most common causes of shoulder pain and can cause rotator cuff tendinitis.[1,2] SIS is caused by narrowing of the subacromial space due to various causes[3] and can cause shoulder pain, limitation of movement, and loss of strength.[4,5] Currently, treatments for SIS include medications such as analgesic agents, conservative therapies such as exercise and physical therapy, and injection therapy.[6] Steroid injections are the most commonly used treatment if conservative therapy fails.[7] However, the effectiveness of steroid injection is controversial and might be harmful if abused in tendon tissue.[8-10]

Acupuncture has often been applied as an effective alternative treatment for many musculoskeletal disorders and chronic pain.[11] For shoulder pain, acupuncture is thought to have the effects of pain relief, improvement of range of motion, and improvement of shoulder function.[12] Another previous study on SIS demonstrated

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https://doi.org/10.1016/j.imr.2020.100693

the effectiveness of acupuncture and exercise therapy in improving the function of the shoulder.[13]

In the course of injection treatment for SIS, it is believed that it is important to accurately treat the subacromial space.[14,15] However, the subacromial space is not anatomically wide, and it is difficult to accurately inject into the space.[14] In acupuncture treatment, which determines the depth of insertion based on proportional measurements without the use of imaging devices, it may be more difficult to accurately insert a needle into the space.

Therefore, in this study, we used a low-dose X-ray fluoroscopic device to accurately guide the acupuncture needle into the subacromial space. We evaluated the effectiveness and safety of LA for SIS compared with acupuncture without fluoroscopy.

2. Methods

2.1. Study design and ethics approval

This study consisted of a randomized, patient-assessor blind, controlled clinical trial with two parallel groups. The protocol of this study was approved by the institutional review board of Wonkwang University Gwangju Medical Center (WKIRB-2017/13) on 28 October 2017 and was published as a paper.[16] The trial was conducted according to the ethical principles of the Helsinki Declaration. Subjects were recruited at Wonkwang University Gwangju Medical Center in Korea from October 2017 to December 2018 through posters and advertisement in the medical center. Subjects who voluntarily signed consent forms were evaluated by a screening test, and eligible subjects were randomly assigned to one of two parallel groups. The LA group received acupuncture treatment with fluoroscopy guidance, and the CA group received acupuncture treatment with only palpation guidance and proportional measurements. The total duration of the study was three weeks, including two weeks of follow-up periods. Subjects received acupuncture treatment at baseline and after one week. The progress of the study is summarized in Supplement 1.

2.2. Inclusion and exclusion criteria

Subjects who met the following criteria were enrolled.

(1) Males or females age 25 to 65 years old, with no limitation of range of shoulder motion
(2) Those diagnosed with SIS by excluding fracture, dislocation, degenerative arthropathy, os acromiale, subacromial spur, and calcific tendinitis in plain radiography
(3) Those with shoulder pain lasting more than 2 months from onset and pain that is worsened when sleeping sideways or lifting the arm over the head, with a positive result on the Neer or Hawkins test, with more than 50 mm on pain of VAS
(4) Those able to communicate sufficiently with the researcher and write a questionnaire with minimal help
(5) Those who have pledged not to receive treatment other than the prescribed treatment within the period of study
(6) Those who voluntarily provide written informed consent.

The exclusion criteria are described as follows:

(1) Those with a trauma history of shoulder surgery, fracture, dislocation;
(2) Those with disorders of the cervical spine or upper extremity that have a significant impact on the shoulder;
(3) Those who received injection treatment on the shoulder within 6 months;
(4) Those with fracture, dislocation, degenerative arthropathy of the glenohumeral joint or acromioclavicular joint, os acromiale, subacromial spur and calcific tendinitis of the shoulder in plain radiography;
(5) Those with positive findings in the physical examination (drop arm test, empty can test) for exclusion of rotator cuff tears;
(6) Those with positive findings in the physical examination (Yergason test) for exclusion of biceps tendinitis;
(7) Those diagnosed with a frozen shoulder (adhesive capsulitis) in the range of motion test;
(8) Those with clinical conditions in internal medicine (pacemaker insertion, significant arrhythmia on electrocardiography, etc.);
(9) Pregnant or breastfeeding female patients, with positive findings in the urine pregnancy test before random assignment and those who are unable or unwilling to use contraceptive methods (hormonal contraceptives, condoms, intrauterine devices, etc.) to avoid pregnancy throughout the entire study period;
(10) Those with mental disorders who cannot follow the protocol;
(11) Those considered unsuitable for participation by the researcher.

2.3. Randomization and blinding

Randomization was conducted by an independent researcher using SAS ver.9.0 for Microsoft Windows (SAS Institute Inc., NC, Cary, USA). Block randomization was carried out, and the block size was 4. Sealed blind envelopes were used for the randomization process. Random number generation and storage of envelopes was independently managed by a third researcher. For blinding, the practitioner performed the treatment session only and minimized conversation with subjects, and the assessors performed the assessments independently. The practitioner, assessors, statisticians, and all related study staff did not know of the allocation, and the blinding was maintained until the end of the trial.

2.4. Interventions

Enrolled subjects received total 2 sessions of acupuncture treatment. The details of the time points are shown in Supplement 1. The details of the acupuncture treatment based on the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) are described in Supplement 2. After completion of each treatment session, the low-dose X-ray device was used to evaluate the accuracy of whether the acupuncture needle was successfully inserted in the subacromial space or not. The low-dose X-ray device used in the clinical trial was a portable X-ray imaging device with low-dose radiation exposure. The product name is NFR MX-DRF0815 (Korea, NanoFocusRay Co., Ltd).

2.4.1. Low-dose X-ray guided acupuncture (LA) group

Subjects in the experimental group received LA to the subacromial space. The acupuncture points were LI15, TE14, and LI16 on the side of the affected shoulder. Acupuncture treatment was performed for 15 min with needle manipulations using disposable sterile acupuncture needles (0.40 × 50 mm, Dongbang, Republic of Korea). For acupuncture guidance, we used the portable low-dose X-ray device. Before the acupuncture treatment, the shoulder anterior-posterior (AP) view was captured in radiography mode to confirm the subacromial space. We performed the acupuncture treatments with the low-dose X-ray guide in fluoroscopy mode.

2.4.2. Conventional acupuncture (CA) group

Subjects in the control group received acupuncture treatments with proportional measurements and without use of the low-dose X-ray device. The acupuncture points were same as in the experimental group, and the locations and depths of the acupuncture points were determined according to proportional measurements and the Korean Medicine Convergence Research Information Center (KMCRIC) standard acupuncture point guideline, which is based on the WHO/WPRO standard acupuncture point locations.[17]

2.4.3. Concomitant treatment

Patients who take low dose of aspirin (maximum 200 mg per day) for prevention of stroke were acceptable. Any analgesics for pain relief, muscle relaxants, antidepressants, anticonvulsants, physical therapy, injection, and treatments performed by other hospitals for pain relief during the study period were prohibited. However, it was acceptable to cease medicines 1 week before the trial. Concomitant treatment, which had occurred since 4 weeks before the enrollment, was allowed only if it was judged by the researcher to not affect the test results.

2.5. Outcomes

2.5.1. Primary outcome

The primary outcome was the change of 100 mm VAS for shoulder pain after one week from the baseline. The degree of pain felt during the Neer test and Hawkins test were checked using the 100 mm line, which is described at the end as "no pain" and at the other end as "worst pain imaginable".

2.5.2. Secondary outcomes

The secondary outcomes were the incidence rate of impingement sign and function of the shoulder joint. These outcomes were measured at baseline, one week and three weeks. To assess incidence rate of impingement sign, we performed the Neer test and Hawkins test.[18] The function of the shoulder joint was assessed by the modified CMS and the SPADI. We also evaluated the accuracy rate of acupuncture. The change values from the baseline at one week and three weeks were compared between two groups.

2.5.3. Safety evaluation

We checked vital signs at every visit. We checked on adverse events (AEs) and serious adverse events (SAEs) at every visit of the study. For AEs and SAEs, we recorded the onset date, end date, intensity, relationship with the clinical trial, result, and action taken on the AE.

2.5.4. Accuracy rate of acupuncture treatment

The shoulder standard AP view and scapular Y view were captured after acupuncture treatment to confirm that the acupuncture needle was accurately inserted into the subacromial space. An X-ray was taken at baseline and at one week where the acupuncture treatment performed. A radiologist assessed the accuracy of acupuncture. If the tip of the needle was inserted into the subacromial space, it was evaluated as a success, and if it was inserted in a place other than the subacromial space (e.g., connective tissue such as the deltoid muscle), it was classified as a failure. The X-ray images in this trial are presented in Supplement 3 for better understanding. The number of needles successfully inserted into the subacromial space was analyzed and compared between two groups.

2.6. Sample size

Because the hypothesis of our study was that the effectiveness of acupuncture treatment with low-dose X-ray guidance is superior to that of the control treatment, one-tailed power analysis by the continuous outcome superiority trial was determined. To calculate the sample size, we searched previous studies to determine the significant difference of VAS. There was no study with the same group and same primary outcome settings as our study. Therefore, referring to the previous clinical trial including a broad population of patients with various musculoskeletal conditions, we determined a significant difference of VAS as 2 points.[19-21] From the study comparing fluoroscopy-guided and blind corticosteroid injections, the standard deviation (SD) was conservatively assumed to be 2.3.[22] We calculated the sample size with 80% power at a significance level of 0.05. The sample sizes were 42 in total and 21 for each group. We considered the dropout rate as 20%, and the sample size was determined as a total of 54 subjects.

2.7. Statistical analysis

All statistical analyses were performed by the SPSS program (Statistics for Windows Version 22.0, Armonk, NY, IBM Corp). We used the full analysis set for effectiveness variables and the safety set for safety variables. In the case of a full analysis set, after assignment to the group, all subjects were analyzed according to the intention to treat principle, regardless of compliance with the protocol. In the case of the safety set, all subjects who received treatment at least once after the assignment were included in the analysis. The primary outcome was the change of pain intensity measured by VAS after one week compared to baseline. To compare the VAS change between two groups, a two sample *t*-test was conducted. The paired *t*-test was used to evaluate the difference before and after the treatment in each group. For the interaction of treatment over time, repeated measures analysis of variance (RM-ANOVA) was conducted. The secondary outcomes (modified CMS and SPADI) were evaluated by the same methods as the primary outcome. The incidence rates of shoulder impingement sign were summarized in terms of frequency and percentage, and comparison between the two groups was performed using the Chi-square test or Fisher's exact test. The number of accurately inserted needles of each group was compared via the two-sample *t*-test.

For safety evaluation, the two-sample *t*-test or Mann-Whitney *U* test was conducted in the case of continuous variables, and the Chi-square test or Fisher exact test was conducted for assessment of the differences of incidence of AEs. In the case of missing data, the method of last observation carried forward (LOCF) was used.

2.8. Data management

All trials were recorded in accordance with the standard operating procedure of the clinical trial center. All data and source documents were archived with whole backup in the clinical trial center computer system.

3. Results

3.1. Flow of participants and demographic data

Of seventy-eight subjects applied to this trial, a total of 54 subjects were enrolled after the screening test (Fig. 1). During the trial, one subject dropped out due to an AE not related to the trial (herpes zoster) in the CA group. The general characteristics of the study subjects are summarized in Table 1, and no statistically significant differences were observed between the two groups.

3.2. Outcome measures

3.2.1. Primary outcome

The pain intensity during the Neer test and Hawkins test was significantly reduced at one week in both the LA and CA groups. In terms of the amount of change in VAS at one week from baseline, the change in the LA group was larger than that in the CA group during the Neer test (p=0.008). No difference was observed between the two groups during the Hawkins test (Table 2). The results of the RM-ANOVA analysis are presented in Supplement 4.

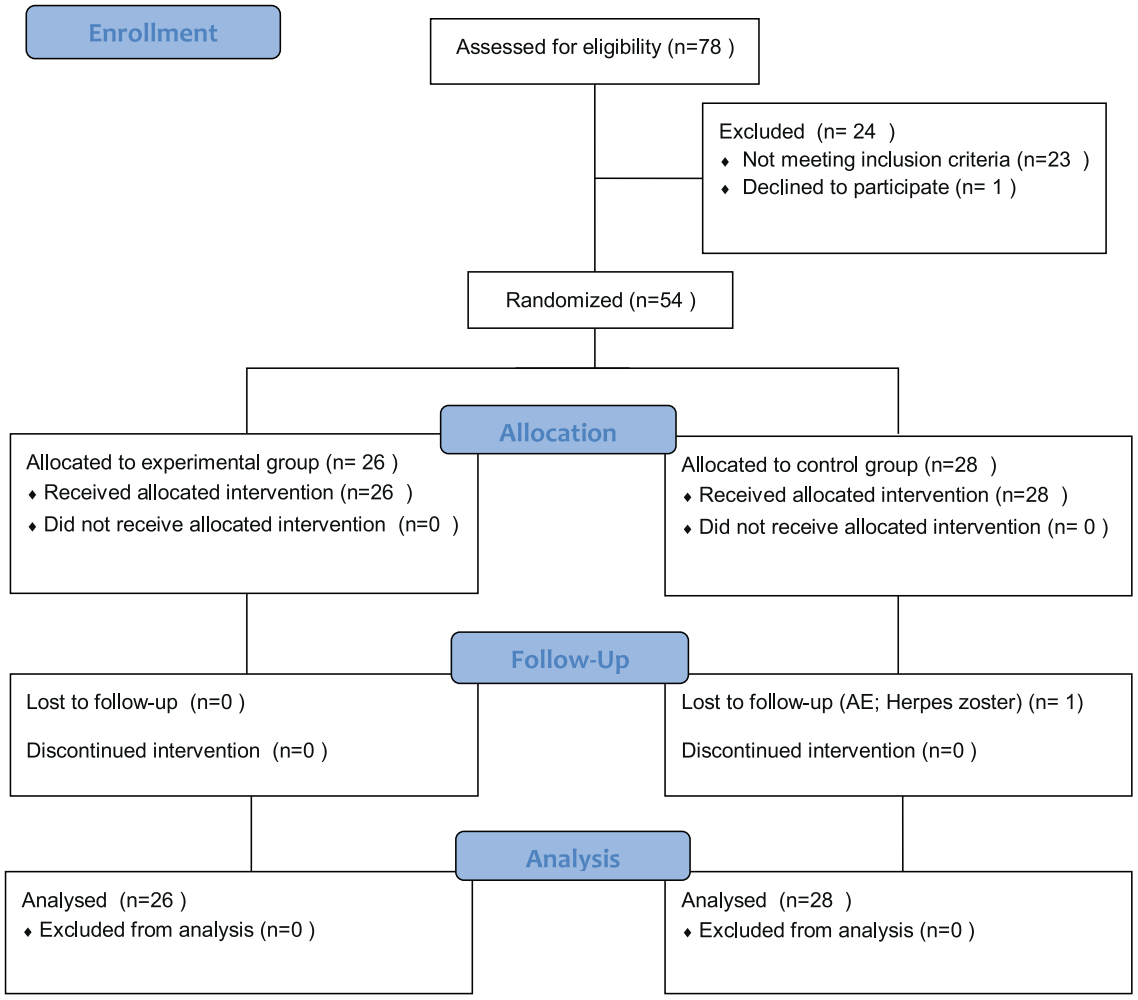

Fig. 1. The flowchart of the study.

Table 1
Demographic data of participants.

	LA group (n = 26)	CA group (n = 28)	P (t or χ^2 test)
Age (year)_	46.23 ±9.86	47.07±7.07	0.77
Height (cm)	165.19±6.35	165.10±65.1	0.97
Weight (kg)	63.11±3.11	65.03±5.03	0.55
Duration from onset (month)	19.57±9.57+	16.53±6.53+	0.64
Sex, n (Male Female)	10/16	12/16	0.74
Lesion side, n (Rt/Lt)	16/10	17/11	0.95
Experience of treatment, n (Yes/No)	5/21	8/20	0.42

The results are expressed as the mean ± standard deviation values or number (n)
CA, Conventional acupuncture; LA, Low-dose X-ray guided acupuncture.

3.2.2. Secondary outcomes

Incidence of pain during impingement test: no significant differences were noted between the two groups in incidence of pain during the Neer test and Hawkins test (Supplement 5).

Shoulder function measured by modified CMS score: the change in total CMS score before and after treatment at one week and three weeks did not show a significant difference. The results from the RM-ANOVA analysis are shown in Supplement 6.

Shoulder pain and function measured by SPADI score: the change in SPADI before and after treatment at one week did not show a significant difference between the two groups. In a comparison at the follow-up period after three weeks, all categories of SPADI were improved more significantly in the LA group (Table 2). The additional analysis with RM-ANOVA analysis can be found in Supplement 76.

3.3. Safety evaluation

There were no SAEs. One AE case occurred during the trial in the control group. The reported AE was herpes zoster in the cervical region, which occurred after the second treatment. The subject was dropped because the trial could not be continued for treatment of related symptoms, and the symptom was lost after the treatment. The vital sign changes before and after the treatment were not statistically significant in both groups and in the between group comparison.

Table 2
Change in outcome variables of shoulder pain and function in each group.

	LA group (n=26)					CA group (n=28)					P	
	Baseline	1 week	3 week	Δ1	Δ 2	Baseline	1 week	3 week	Δ1	Δ 2	P (Δ 1)	P (Δ 2)
Pain (VAS)												
Neer test	62.5 ±22.3	34.0 ±24.0	37.1 ±25.3	28.5 ±24.5**	25.4 ±27.6**	55.8 ±19.6	42.8 ±20.2	44.8 ±25.4	13.0 ±16.5**	11.0 ±24.1*	.008†	.045†
Hawkins test	66.4 ±17.6	38.2 ±26.8	39.2 ±26.2	28.2 ±25.6**	27.2 ±26.7**	63.3 ±18.2	46.2 ±25.1	44.5 ±23.6	17.1 ±22.7**	18.8 ±27.5*	.097	.263
CMS												
Pain	5.4 ±2.5	6.9 ±4.1	8.5 ±3.6	1.5 ±3.1*	3.2 ±3.5**	6.2 ±2.3	6.3 ±3.2	7.6 ±3.5	0.4 ±2.6	1.4 ±3.3*	.076	.066
Daily activities	14.1 ±3.1	16.5 ±2.9	17.7 ±2.9	2.5 ±2.5**	3.6 ±3.2**	13.8 ±3.8	15.3 ±3.1	16.3 ±3.2	1.4 ±3.5*	2.5 ±5.3*	.216	.351
ROM	31.5 ±6.2	32.9 ±5.1	34.5 ±4.8	1.4 ±4.9	2.9 ±3.8*	29.5 ±5.2	33.4 ±5.1	31.8 ±4.9	3.8 ±5.2**	2.2 ±4.1*	.088	.494
Muscle strength	9.0 ±5.4	9.6 ±4.8	10.0 ±5.6	0.5 ±4.8	0.9 ±5.5	10.5 ±6.2	10.1 ±5.7	11.4 ±6.8	-0.4 ±4.8	0.9 ±6.1	.476	.967
Total	60.0 ±12.1	65.9 ±12.8	70.6 ±11.8	5.8 ±8.3**	10.6 ±8.2**	60.6 ±11.2	64.0 ±13.6	67.1 ±13.0	3.4 ±10.6	6.5 ±10.9*	.350	.126
SPADI												
Pain	63.8 ±15.6	50.4 ±19.6	39.2 ±19.3	13.5 ±14.1**	24.7 ±18.0**	63.6 ±15.7	56.1 ±18.2	50.9 ±22.1	7.5 ±14.9*	12.7 ±22.7*	.138	.037†
Disability	44.2 ±21.7	37.9 ±19.4	28.2 ±18.2	6.3 ±17.9	16.0 ±21.8*	40.1 ±21.9	39.7 ±23.3	36.8 ±21.8	0.5 ±17.8	3.3 ±18.1	.236	.021†
Total	51.7 ±17.9	43.1 ±18.2	32.4 ±17.6	8.7 ±14.4*	19.3 ±18.9**	49.7 ±18.1	45.8 ±20.2	42.2 ±20.7	3.9 ±15.2	7.5 ±17.5*	.244	.024†

Values are presented as the mean ± standard deviation. Δ 1: Changes between baseline and 1 week; Δ 2: Changes between baseline and 3 weeks
CA, Conventional acupuncture; CMS, Constant-Murley shoulder outcome; LA, Low-dose X-ray guided acupuncture; SPADI, Shoulder Pain and Disability Index; VAS, Visual analogue scale
* P<0.05
** P<0.001: paired t-test within group.
† P<0.05: unpaired t-test between groups.

3.4. Accuracy of acupuncture treatment

The number of accurately inserted needles was significantly different between the two groups. At the first treatment at baseline, the numbers of needles accurately located in the subacromial space were 1.38±0.804 in the LA group and 0.07±0.262 in the CA group (p=0.000), and at the second treatment at one week, these numbers were 1.54±0.761 in the LA group and 0.07±0.262 in the CA group (p=0.000).

4. Discussion

As a result of this trial, both LA and CA treatment showed a significant effect in alleviating shoulder pain and function. Additional RM ANOVA showed that LA and CA may have some differences in therapeutic effect in terms of pain relief and functional recovery over time. According to the accuracy test of the acupuncture treatment, LA treatment was more accurate than CA treatment for insertion of the acupuncture needle into the subacromial space.

In previous studies, a meta-analysis study analyzed the effect of acupuncture on chronic musculoskeletal pain such as osteoarthritis and shoulder pain. It was found that acupuncture was more effective than the sham acupuncture or no-acupuncture control groups, and the effect lasted over time.[11] In addition, the effects of acupuncture on pain relief and functional improvement were also found in several RCTs that performed acupuncture in chronic shoulder pain and SIS patients.[12,13] The effects of pain relief and function improvement in both the LA and CA groups in this study are consistent with the results of previous studies. However, this is the first study to compare the effect of LA with the effect of CA, and this study is meaningful in that it proposes a new method of acupuncture treatment by proving the superiority of LA in terms of accuracy and effectiveness on shoulder pain and function as measured by VAS and SPADI.

We only applied two sessions of treatment with the expectation that the therapeutic effect appears in the short term because the intervention in this trial treats the subacromial space more directly than conventional treatment. To yield meaningful results for the outcomes that were not proved to be significant in this study, it is thought that the number of samples and the duration of treatment should be increased. The treatment period and frequency should be longer than at least 4 weeks and consist of more sessions in reference to other studies that use acupuncture treatment as an intervention in shoulder pain.[23-26] The amount of change in the Hawkins VAS, which is one of the primary outcomes in this study, was 28.19 in the LA group and 17.09 in the CA group. Assuming 80% power and a significance level of 5%, 136 subjects will be required to verify this outcome in future studies.

As a limitation of this study, it was impossible to blind the practitioner due to the characteristics of the intervention. Therefore, performance bias cannot be ruled out, and the results should be interpreted carefully. Some might question the discrepancy in sample numbers between the LA and CA groups. A mistake was made by the third researcher in the process of implementing block randomization with block size 4. Because the total sample size was 54, only 3 additional subjects should have been allocated to the CA group after filling up to 24 subjects, but the researcher mistook the total sample size as 56 and incorrectly set 28 subjects for the CA group. Therefore, the number of subjects in the LA group was only 26. It was difficult to recruit additional subjects by changing the sample size, and those who had already been assigned to the CA group could not be changed to the LA group. Thus, the trial was conducted with this discrepancy. To confirm the prior homogeneity of the two groups, the demographic data of the two groups were compared. No statistically significant differences in gender, age, weight, height, duration, lesion side and experience of treatment were observed.

Vital signs remained stable during the treatment period, and there were no adverse reactions except for one case of herpes zoster, which was not related to the clinical trial intervention, and thus the intervention in this trial is considered safe.

The intervention method of directly treating the anatomically problematic space by monitoring the process of acupuncture with a low-dose X-ray device has not been previously attempted. This method is thought to be meaningful in increasing the therapeutic effect of acupuncture, as shown by the result of this study. It is expected that further related studies can be conducted, such as a comparative study with conventional acupuncture or analysis of combined treatment effects. Because an economic assessment was not included in this study, an economic evaluation that analyzes the cost effectiveness of the fluoroscopic guide acupuncture should be conducted in further research.

In conclusion, LA is thought to be more effective than CA in alleviating pain and improving the function of the shoulder. Further studies are needed to prove the effectiveness on other outcomes and to evaluate the cost-effectiveness.

Conflict of interest

The authors have no conflicts of interest to declare.

Funding

This study was supported by the Traditional Korean Medicine R&D program funded by the Ministry of Health & Welfare through the Korea Health Industry Development Institute (KHIDI) (HI14C0665).

Ethical statement

This research was approved by the institutional review board (IRB) of Wonkwang University Gwangju Medical Center (WKIRB-2017/13) on 28 October 2017. Written informed consent was obtained from the participants for treatment and for publication.

Data availability

Data will be made available upon request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2020.100693.

CRediT authorship contribution statement

Hee-Ra Shin: Conceptualization, Methodology, Writing - original draft. **Jihye Seo:** Conceptualization, Methodology, Validation, Investigation, Writing - review & editing. **Kyungtae Park:** Software, Validation, Formal analysis, Investigation, Writing - review & editing. **Sung-Hu Ann:** Software, Formal analysis, Investigation, Writing - review & editing. **Soo-Ji Park:** Resources, Data curation, Visualization. **Sangkwan Lee:** Writing - review & editing, Project administration, Funding acquisition. **Seung-Ryong Yeom:** Conceptualization, Methodology, Writing - review & editing, Supervision, Project administration, Funding acquisition.

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