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Review Article

Acupuncture for Symptomatic Rotator Cuff Disease: A Systematic Review and Meta-Analysis

Seoyoung Choi [1], Jisun Lee [1], Seunghoon Lee [2], Gi Young Yang [1, 3], Kun Hyung Kim [1, 3,*]

1 Department of Acupuncture and Moxibustion Medicine, Pusan National University Korean Medicine Hospital, Yangsan, Korea
2 Department of Acupuncture and Moxibustion, College of Korean Medicine, Kyung Hee University, Seoul, Korea
3 Division of Clinical Medicine, School of Korean Medicine, Pusan National University, Yangsan, Korea

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ABSTRACT

The objective was to evaluate the effectiveness and safety of acupuncture for patients with rotator cuff diseases.
There were 12 electronic databases and 3 trial registries searched up to November 30th, 2019. All randomized trials were eligible, regardless of language, date of publication, or settings. The primary outcomes were pain, shoulder function, and proportion of improved participants assessed within 12 weeks of randomization of the trial. The Cochrane risk of bias for the studies was assessed. Effects sizes were presented as a risk ratio, mean difference, or standardized mean difference with a 95% confidence intervals. Grading of Recommendations Assessment, Development and Evaluation approach was adopted to rate certainty of evidence.
Of the 3,686 records screened, 28 randomized trials (2,216 participants) were included in this review. The types of acupuncture included manual acupuncture, dry needling, electroacupuncture, acupotomy, warm needle acupuncture, and fire needle acupuncture. All of the studies had an unclear or high risk of bias related to more than 1 domain. Significant benefits of acupuncture in terms of pain and shoulder function were observed in all comparisons, however, the proportion of improved participants was not described in 2 comparisons. There was substantial heterogeneity among meta-analyzed trials. No serious harm was observed. For primary outcomes, the overall certainty of evidence was very low.
There was very low certainty of evidence for the benefits of acupuncture for patients with rotator cuff diseases. The safety of acupuncture remains unclear due to the incompleteness of reporting. Future well-designed randomized trials with transparent reporting are required.

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Introduction

Shoulder pain is a common musculoskeletal complaint, and an important medical and socioeconomic problem [1]. Rotator cuff diseases (RCDs) are the most common cause of shoulder pain [2], and encompass a broad spectrum of pathology and anatomical deformities, including shoulder impingement syndrome, rotator cuff (RC) tendinopathy or tendinitis, partial or full RC tear, calcific tendinitis, subacromial bursitis, and subacromial pain syndrome [3,4].

Pathogeneses of RCD incorporate repeated impingement of RC tendons against extrinsic factors such as acromial osteophytes, intrinsic RC tendon degeneration which makes itself susceptible to impingement due to dynamic instability of the glenohumeral joint, or a combination of these factors [3,5]. Available treatments include analgesics, non-steroidal anti-inflammatory drugs, exercise, local corticosteroid injection, and surgery. Whether they are beneficial for functional recovery in the shoulder remains mostly inconclusive due to paucity of high-quality of evidence [6].

There is evidence to suggest that there are benefits of acupuncture for treating shoulder pain [7]. However, previous systematic reviews have included mixed groups of patients with shoulder pain which may have rendered study findings susceptible to clinical heterogeneity [8-10]. The various types of acupuncture, commonly practiced in East Asia, were not fully considered as intervention of interest, which implied limited scope of evidence,

*Corresponding author. Kun Hyung Kim
Department of Acupuncture and Moxibustion Medicine, Pusan National University Korean Medicine Hospital, Geumo-ro 20, Mulgeum-eup, Yangsan, 50612, Korea
E-mail: pdchrist@gmail.com
ORCID: Seoyoung Choi https://orcid.org/0000-0003-0108-8617, Jisun Lee https://orcid.org/0000-0003-1019-1675, Seunghoon Lee https://orcid.org/0000-0003-0088-2296, Gi Young Yang https://orcid.org/0000-0002-9468-8904, Kun Hyung Kim https://orcid.org/0000-0002-3471-2431

and a gap between current practice [8,9,11]. Methodological limitation included exclusion of studies in languages other than English [8], and lack of prospective registration [11]. Collectively, caveats of evidence for the role of acupuncture for treatment of RCD justifies conducting an updated systematic review with clear focus on the RCD, comprehensive search strategy, and rigorous methodology.

The purpose of this systematic review was to assess the effectiveness and safety of acupuncture treatments for managing symptoms and shoulder function in patients with RCDs.

Materials and Methods

The protocol for this study was prospectively registered on the Open Science Framework (OSF) registries (available on osf.io/n2e6t), and the International prospective register of systematic review (PROSPERO, registration no.: CRD42020154235). Details of the methods in this study have been reported previously [12].

Criteria of study selection

Randomized controlled trials (RCTs) of acupuncture, which were classified as a "needle stimulation" (penetration of the skin and the resultant de-qi sensation), regardless of the methods of stimulation or type of needles (e.g., electroacupuncture (EA), pharmacopuncture, thread-embedding therapy, and acupotomy), stimulating points (e.g., auricular points, scalp acupuncture points, and tender points), duration, or number of treatments were included. There were no restrictions by language, date of publication, settings, or locations of the study. Patients who had been diagnosed with RCDs based on clinical assessments with or without radiological evidence (e.g., ultrasound, magnetic resonance imaging) were included. The trials of patients with pain in the shoulder or upper extremity due to pathologies not related to the rotator cuff, such as fractures, osteoarthritis, adhesive capsulitis, or hemiplegic shoulders were excluded. There were no restrictions on age, sex, or ethnic origin. Control interventions included active treatments other than different types of acupuncture or acupoint-related treatments, placebo, or no treatment. Quasi-randomized or non-RCTs were excluded.

Types of outcome measures

The collected data was classified for all the time points of assessment as short-term (up to 3 months post-randomization), intermediate-term (up to 6 months post-randomization), and long-term (more than 6 months post-randomization). The primary and secondary outcomes are presented in Table 1.

Search strategy

There were 12 electronic databases (Table 2) searched up to November 30th, 2019. There were 3 trial registries checked, and references of the trials, and reviews. Study protocols or conference abstracts, were tracked to determine whether they had been published. The search strategies applied to each database are shown in Appendix A.

Table 1. Primary and Secondary Outcomes.

Primary outcomes
• Pain measured on assessment instruments, such as VAS or NRS, within 12 weeks.
• Shoulder function measured on assessment instruments, such as CMS, SPADI, DASH score, UCLA Shoulder rating scale, or ASES rating scale, within 12 weeks.
• Proportion of improved participants within 12 weeks.
Secondary outcomes
• Pain measured on assessment instruments, such as the VAS or NRS, over 12 weeks.
• Shoulder function measured on assessment instruments, such as the CMS, SPADI, DASH score, UCLA Shoulder rating scale, or the ASES rating scale, over 12 weeks.
• Health-related quality of life measured on assessment instruments such as SF-36 Health Survey or EQ-5D.
• Patient global assessment of treatment outcomes, such as Patient Global Impression of Change.
• Occurrence of adverse events.
• Active range of motion of shoulder joint.
• Muscle strength.
• Work disability, such as length or total days of sick leave.
• Proportion of patients who finally ended up receiving shoulder surgery.

VAS, visual analogue scale; NRS, numeric rating scale; CMS, Constant-Murley score; SPADI, Shoulder Pain and Disability Index; DASH, Disabilities of the Arm, Shoulder and Hand; UCLA, University of California-Los Angeles; ASES, American Shoulder and Elbow Surgeons; SF-36, Short-Form 36; EQ-5D, EuroQoL-5D.

Table 2. Electronic Databases Searched.

English databases
• MEDLINE, EMBASE, CENTRAL, CINAHL, AMED, & PEDro
Chinese databases
• CAJ
Korean databases
• KISS, NDSL, RISS, KMBASE, & OASIS
Trial registries
• ClinicalTrials.gov, ISRCTN Registry, & WHO ICTRP

CENTRAL, Cochrane Central Register of Controlled Trials; CINAHL, Cumulative Index to Nursing and Allied Health Literature; AMED, Allied and Complementary Medicine; PEDro, Physiotherapy Evidence Database; CAJ, China Academic Journal Full-text Database; KISS, Korean studies Information Service System; NDSL, National Digital Science Library; RISS, Research Information Sharing Service; KMBASE, Korean Medical Database; OASIS, Oriental Medicine Advanced Searching Integrated System; ISRCTN, International Standard Randomized Controlled Trials Number; ICTRP, International Clinical Trials Registry Platform.

Data collection and analyses

One reviewer searched for the studies. Two reviewers independently assessed eligibility of studies. Disagreements between the two review authors were discussed with a third reviewer. One reviewer extracted the relevant data other than information on risk of bias assessment. The details of the intervention were summarized based on the revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) [13]. Two reviewers independently assessed the risk of bias, according to the Cochrane Handbook for Systematic Reviews of Interventions [14].

Dichotomous outcomes were presented as risk ratios (RR), and continuous outcomes as the mean difference (MD) or standardized mean differences (SMD) with 95% confidence intervals. Multiple acupuncture groups in a trial were combined for pairwise comparison. In case of multiple outcome measurements within the same time frame (short, intermediate, or long term), the last measurement data within that time frame was used. An attempt to contact the corresponding author was made in each study to obtain missing or unclear information; missing values were not imputed other than sensitivity analysis. For the assessment of heterogeneity, we calculated the I^2 statistic. An I^2 rate of less than 40% was categorized as low, 30-60% as moderate, 50-90% as substantial, and 75-100% as considerable heterogeneity [14]. RevMan software (Review Manager Version 5.4 for Windows, The Nordic Cochrane Centre, Copenhagen) was used to perform a meta-analysis. A random-effects model was used because substantial clinical heterogeneity amongst the included studies was expected. The pooled effect estimates of all the comparisons were reported, regardless of the observed heterogeneity. A predefined subgroup analysis was performed for (1) diagnosis of the study population (i.e., RC tear or without tear), (2) type of acupuncture stimulation (i.e., manual, electrical, or other stimulation techniques, such as pharmacoacupuncture, acupotomy, or thread-embedding therapy), where meta-analyses of primary outcomes included at least 6 studies. Sensitivity analyses were performed to determine whether the results of the trials were affected by trials where the radiological diagnosis of an RCD was not mentioned in the participant eligibility criteria, or the measures of variance were missing, and by different methods of analysis (random-effects model or fixed-effect model). Where the data of variance were missing, sensitivity analysis was conducted by imputing the largest standard deviation within the same meta-analysis.

Assessing the certainty of evidence

The Grading of Recommendations Assessment, Development and Evaluation approach was adopted to assess the certainty of the evidence for each main outcome, and for reporting adverse events for the following domains: the risk of bias across studies, inconsistency, indirectness, imprecision, and publication bias [15]. The methods and recommendations described in the Cochrane Handbook for Systematic Reviews of Interventions were used for the judgments [14].

Results

Search results

There were 3,686 records identified from English, Chinese, and Korean databases. After the removal of duplicates, the titles and abstracts of 2,654 records were screened. After screening 297 full-text articles, 28 RCTs were included which in total had 2216 participants in the qualitative syntheses, and 27 RCTs were included in the meta-analyses (Fig. 1). Contacting corresponding authors to verify the eligibility of the studies was not possible due to the absence of contact information in the published studies [16,17] or unanswered emails [18-21]. One RCT studying the feasibility of the Park sham needle was excluded because the purpose of the study was to assess the feasibility of the needle and it did not provide clinical outcome results [22]. One study was excluded from the meta-analysis due to errors on the sample size and an absence of reporting on variance of the outcomes [23]. One study was ongoing and was therefore not included in the this current review [24].

Included studies

All studies were parallel-group RCTs. Seven trials had multiple acupuncture arms. Studies were conducted in China (n = 23), Spain (n = 2), Sweden (n = 1), Germany (n = 1), and Greece (n = 1). The number of participants in each study ranged from 30 to 178. The trials included patients with RC (i.e., supraspinatus) tendinitis (n = 9) [23,25-32], RC tear (n = 3) [33-35], RC injury (n = 5) [36-40], impingement syndrome (n = 7) [41-47], subacromial pain syndrome (n = 1) [48], subacromial bursitis (n = 1) [49], and nonspecific shoulder pain (n = 2) [50,51]. Two studies with nonspecific shoulder pain were included, since the eligibility criteria for the trials were deemed consistent with a clinical or radiological diagnosis of RCD [50,51]. Of the 28 trials, 13 studies used both clinical and radiological criteria for the diagnosis of RCD [23,27,29,33-36,39-41,43,49,51]. The types of acupuncture conducted in the 28 studies included manual acupuncture (n = 7) [25,27,33,40,45,49,50], dry needling of trigger points (n = 2) [48,51], a mixture of manual acupuncture and EA (n = 6) [28,34-37,46], EA (n = 2) [23,44], acupotomy (n = 10) [26,29-32,38,39,41-43], warm needle acupuncture (n = 1) [47], and fire needle acupuncture (n = 1) [30]. One RCT used two different styles of acupuncture arms (i.e., fire needle acupuncture, acupotomy, and fire needle

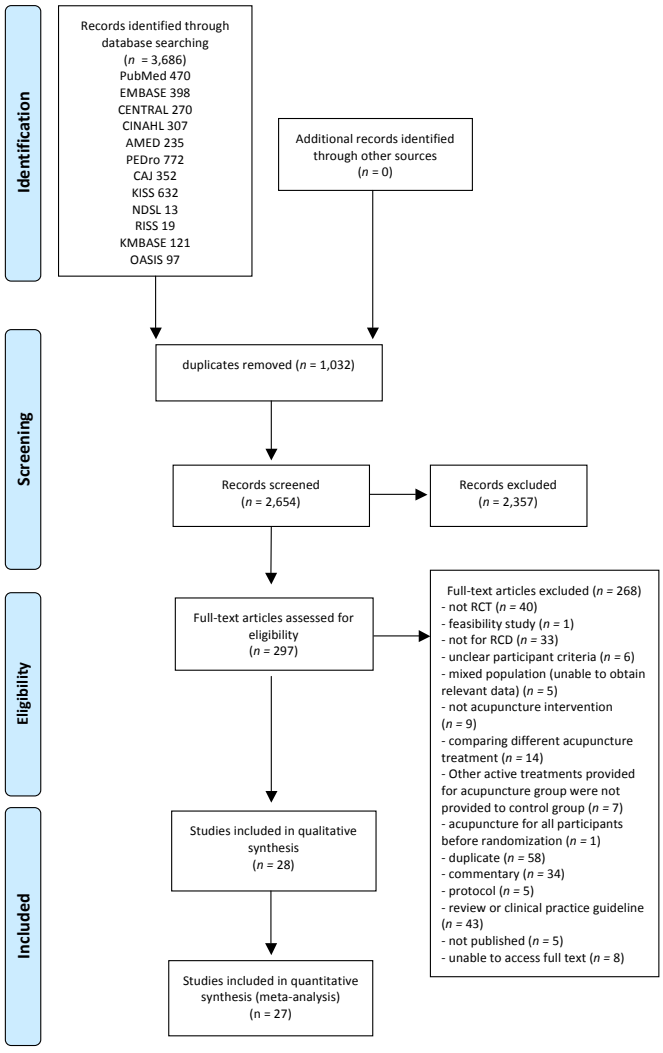

Fig. 1. PRISMA flow diagram of study selection.
CENTRAL, Cochrane Central Register of Controlled Trials; CINAHL, Cumulative Index to Nursing and Allied Health Literature; AMED, Allied and Complementary Medicine; PEDro, Physiotherapy Evidence Database; CAJ, China Academic Journal Full-text Database; KISS, Korean studies Information Service System; NDSL, National Digital Science Library; RISS, Research Information Sharing Service; KMBASE, Korean Medical Database; OASIS, Oriental Medicine Advanced Searching Integrated System; RCT, randomized controlled trial; RCD, rotator cuff disease; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

acupuncture plus acupotomy) [30]. The details on the acupuncture characteristics of the included studies are presented in Table 3. A total of 15 trials reported both pain and shoulder function using validated scales. The most frequently used measurement scales for functional status of the shoulder were the Constant-Murley score [52] (n = 10) and the University of California-Los Angeles (UCLA) shoulder rating scale [53] (n = 9). Seventeen trials from the 23 Chinese studies reported the proportion of improved participants after treatment [25,26,28,30-33,37,39-44,46,47,49]. One trial reported a successful outcome defined by a 50% improvement in the disabilities of the arm, shoulder, and hand score [48]. Quality of life was reported in one trial using subdomains of the Short-Form 36 (SF-36) Health Survey [50]. Fourteen trials reported

Table 3. Characteristics of Acupuncture Treatments (N = 29).

Characteristics	n (%)
Style of acupuncture	
Combination of traditional Chinese & Western medicine	1 (3.4)
Traditional Chinese techniques (meridian points plus ashi points)	16 (55.2)
Western (trigger points)	2 (6.9)
Acupotomy	10 (34.5)
Point prescription	
Fixed needle formula	10 (34.5)
Flexible formula (semi-individualized)	11 (37.9)
Individualized	8 (27.6)
Location of needles	
Both local & distal points	7 (24.1)
Local points only	21 (72.4)
Distal points only	1 (3.4)
Stimulation	
No stimulation	1 (3.4)
Manual plus electrical stimulation	6 (20.7)
Manual stimulation	18 (62.1)
Electrical stimulation	2 (6.9)
Warm needle or fire needle	2 (6.9)
Depth of insertion	
Not reported	12 (41.4)
Osteotendinous junctions	10 (34.5)
0.3-1.5 cun	3 (10.3)
10-35 mm	4 (13.8)
Needle type	
0.25 × 25 mm – 70 mm	9 (31.0)
0.30 × 30 mm – 75 mm	7 (24.1)
0.35 × 40 mm – 50 mm	2 (6.9)
0.40 × 30 mm, 0.40 × 50 mm	2 (6.9)
0.60 × 40 mm – 50 mm	2 (6.9)
0.80 × 31 mm, 0.80 × 50 mm, 0.80 × 90 mm	5 (17.2)
Not reported	4 (13.8)
De-qi sought	
Reported	12 (41.4)
Not reported	17 (58.6)
Maximum number of sessions	
1-5	12 (41.4)
6-10	5 (17.2)
11-15	2 (6.9)
16-20	2 (6.9)
21-25	1 (3.4)
26-30	5 (17.2)
Not reported	2 (6.9)
Frequency of sessions (mean no. sessions/wk)	
≤ 1	11 (37.9)
1 <, ≤ 2	5 (17.2)
3-4	2 (6.9)
5	4 (13.8)
6	1 (3.4)
7	4 (13.8)
Not reported	2 (6.9)
Mean number of needles used	
1-4	3 (10.3)
5-9	7 (24.1)
10-14	1 (3.4)
Not reported	18 (62.1)

Counts sum to 29 (the total number of studies = 28), because one trial had two acupuncture groups, with each group receiving different methods of acupuncture.

whether adverse events occurred [27,28,30-33,35,38,43,45,47-50]. All trials reported outcomes within 12 weeks post-randomization, and 11 trials also assessed outcomes after more than 12 weeks [23,26,27,29,41,42,45,48-51]. Further details on the characteristics of the included studies are presented in Table 4 and Appendix B.

Risk of bias in the included studies

The results of the assessment and the rationale for the decisions are presented in the risk of bias summary (Fig. 2) and the risk of bias tables (Appendix B). Random sequence generation in 14 studies, and allocation concealment in 23 studies were rated as having unclear risk of bias due to insufficient information. Except for the one, patient-blind sham-controlled trial which was rated as having low risk of performance bias [27], the remaining 27 trials were rated as having high risk of bias, because they were open trials. The blinding of the outcome assessment was reported in only 7 trials [23,26,27,45,48,50,51], and the rest of the trials had no descriptions. Most of the trials were rated as having low risk of attrition bias, because they reported no missing outcome data. Twenty-four studies were rated as having unclear risk of reporting bias due to the lack of a study protocol. There were 15 trials rated that did not provide radiological evidence of RCD as having unclear risk of other biases related to the misclassification of RCDs [25,26,28,30-32,37,38,42,44-48,50].

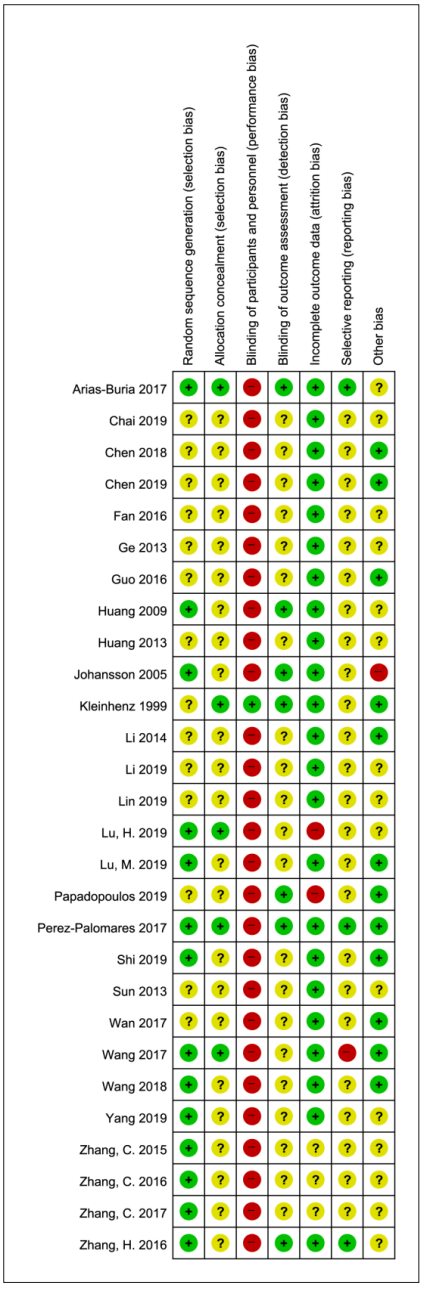

Fig. 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Effects of interventions on pain, shoulder function, and proportion of improved participants

Forest plots based on the analyses are presented in Appendix C. The results of secondary outcomes of each comparison are presented in Table 5. "Summary of findings" tables are presented in Appendix F.

Acupuncture versus sham acupuncture

Manual acupuncture was superior to non-penetrating sham acupuncture in terms of shoulder function as measured using the modified Constant-Murley score at 3 months (n = 52; MD 17.30; 95% CI 7.79 to 26.81) [27].

Acupuncture versus no treatment

Acupotomy treatment of RCDs showed significant reduction of pain intensity measured using the numerical rating scale compared with no treatment at 3 months (n = 52; MD -3.45; 95% CI -4.06 to -2.84) [29].

Acupuncture versus non-pharmacological interventions

Seven studies of acupuncture versus non-pharmacological interventions were included in the analysis [25,26,36,39,44,45,50]. Non-pharmacological interventions included in this comparison were extracorporeal shock wave therapy (ESWT) [25], ultrasound therapy [45], electrotherapy [39], exercises[36,44,50] and manual therapy [26]. Acupuncture showed favorable results on pain reduction measured using VAS scores compared with ESWT, exercise, or electrotherapy combined at 3 months (5 studies; n = 280; MD -1.55; 95% CI -3.05 to -0.04; I^2 = 97%) [25,36,39,44,50], and on shoulder function measured using several scales compared with the exercise, ultrasound therapy, or electrotherapy combined (5 studies; n = 305; SMD 1.56; 95% CI 0.58 to 2.54; I^2 = 93%) [36,39,44,45,50]. Four studies reported the proportion of improved participants measured within 12 weeks [25,26,39,44]. There was no difference between the acupuncture and ESWT, manual therapy, electrotherapy, or exercise combined (4 studies; n = 219; RR 1.07; 95% CI 0.89 to 1.29; I^2 = 69%) [25,26,39,44].

Acupuncture versus pharmacological interventions

Six studies of acupuncture versus pharmacological interventions were included in the analysis [30,41-43,47,49]. Pharmacological interventions included in this comparison were loxoprofen 180 mg per day [30], topical application of diclofenac gel [47], and local corticosteroid (i.e., prednisolone or triamcinolone) or lidocaine injection [41-43,49]. A significant reduction of pain measured using VAS scores compared with the loxoprofen or

Table 4. Summary Characteristics of the Included Studies.

Study ID (Authory [ref])	1) Sample size 2) Diagnosis 3) Country	1) Interventions and controls 2) Session / duration / frequency of acupuncture treatment 3) Session / duration / frequency of other treatments	1) Primary outcomes 2) Total follow-up periods
Arias-Buria 2017 [48]	1) 50 (25/25) 2) Subacromial pain syndrome (clinical) 3) Spain	1) TrP-DN plus exercise (n = 25) versus exercise alone (n = 25) 2) 2 sessions/ 5 weeks/ at the second and fourth sessions among a total of 5 sessions (once a week) 3) Exercise: 5 sessions/ 5 weeks/ once a week (+twice daily for 5 weeks on an individual basis)	1) Function 2) Up to 12 months post-treatment
Chai 2019 [25]	1) 60 (30/30) 2) Supraspinatus tendinitis (clinical) 3) China	1) MA plus topical NSAID (n = 30) versus ESWT plus topical NSAID (n = 30) 2) 14 sessions/ 2 weeks/ 7 times a week 3-1) ESWT: 4 sessions/ 2 weeks/ twice a week 3-2) Topical NSAID: applied for 12h, from 30 min after the end of MA or ESWT.	1) Pain, shoulder abduction ROM, proportion of improved participants 2) 1 week post-treatment
Chen 2018 [36]	1) 178 (89/89) 2) Shoulder impingement syndrome (clinical and imaging) 3) China	1) Acupotomy (n = 89) versus injection therapy (n = 89) 2) 3 sessions/ 3 weeks/ once a week 3) Injection therapy: same as those of acupuncture treatment	1) Function, proportion of improved participants 2) Up to 12 weeks post-treatment
Chen 2019 [41]	1) 40 (20/20) 2) RC injury (clinical and imaging) 3) China	1) EA (n = 20) versus exercise (n = 20) 2) 30 sessions/ 6 weeks/ 5 times a week 3) Exercise: twice daily for 6 weeks on an individual basis	1) Pain, function, shoulder ROM 2) Post-treatment
Fan 2016 [37]	1) 30 (10/10/10) 2) RC injury (clinical) 3) China	1) EA plus electrotherapy and exercise (n = 10) versus EA plus MW and exercise (n = 10) versus electrotherapy, MW and exercise (n = 10) 2) 28 sessions/ 31 days/ once daily, 1 day rest between 7 days of treatment 3-1) Electrotherapy: same as those of acupuncture treatment 3-2) MW: same as those of acupuncture treatment 3-3) Exercise: after each session of the assigned treatment	1) Sub-elements of Constant Murley score: pain, ADL, ROM, strength; proportion of improved participants 2) Mid-/post-treatment
Ge 2013 [42]	1) 120 (60/60) 2) Shoulder impingement syndrome (clinical) 3) China	1) Acupotomy plus manual therapy (n = 60) versus injection therapy plus manual therapy (n = 60) 2) 3-5 sessions/ 3-5 weeks/ once a week 3-1) Injection therapy: 5 sessions/ 5-10 days/ once daily or every other day 3-2) Manual therapy: after each session of the assigned treatment	1) Proportion of improved participants 2) Post-treatment
Guo 2016 [43]	1) 72 (36/36) 2) Shoulder impingement syndrome (clinical and imaging) 3) China	1) Acupotomy (n = 36) versus injection therapy (n = 36) 2) 3 sessions/ 15 days/ once per 5 days 3) Injection therapy: same as those of acupuncture treatment	1) Sub-elements of UCLA shoulder score: pain, function, active forward flexion ROM, strength of forward flexion, patient satisfaction; proportion of improved participants 2) Post-treatment
Huang 2009 [26]	1) 60 (30/30) 2) Supraspinatus tendinitis (clinical) 3) China	1) Acupotomy (n = 30) versus manual therapy (n = 30) 2) Up to 5 sessions/ up to 25 days/ 5 days rest between each treatment 3) Manual therapy: 5 sessions/ 5 days/ once daily	1) Proportion of improved participants, recurrence ratio 2) Up to 3 months post-treatment
Huang 2013 [44]	1) 60 (30/30) 2) Shoulder impingement syndrome (clinical) 3) China	1) EA (n = 30) versus exercise (n = 30) 2) 24 sessions/ 4 weeks/ once a day, 1 day rest after 6 days of treatment 3) Exercise: same as those of acupuncture treatment	1) Pain, function, proportion of improved participants 2) Post-treatment
Johansson 2005 [45]	1) 85 (44/41) 2) Shoulder impingement syndrome (clinical) 3) Sweden	1) MA plus exercise (n = 44) versus ultrasound therapy plus exercise (n = 41) 2) 10 sessions/ 5 weeks/ twice a week 3-1) Ultrasound therapy: same as those of acupuncture treatment 3-2) Exercise: part I, once a day between weeks 1 and 5; part II, once every other day between weeks 4 and 5	1) Function 2) Up to 12 months post-randomization
Kleinhenz 1999 [27]	1) 52 (25/27) 2) RC tendinitis (clinical and imaging) 3) Germany	1) MA (n = 25) versus sham acupuncture (n = 27) 2) 8 sessions/ 4 weeks/ not reported 3) Sham acupuncture: same as those of acupuncture treatment	1) Function 2) Post-treatment
Li 2014 [49]	1) 104 (37/35/32) 2) Subacromial bursitis (clinical and imaging) 3) China	1) Needle pricking plus pharmacopuncture (n = 37) versus needle pricking (n = 35) versus injection therapy (n = 32) 2) 3 sessions/ 3 weeks/ once a week 3-1) Pharmacopuncture: same as those of acupuncture treatment 3-2) Injection therapy: same as those of acupuncture treatment	1) Proportion of improved participants 2) Up to 3 months post-treatment
Li 2019 [38]	1) 160 (30/30) 2) RC injury (clinical) 3) China	1) Acupotomy plus oral Chinese herbal medicine (n = 30) versus oral Chinese herbal medicine alone (n = 30) 2) 8 sessions/ 8 weeks/ once a week 3) Oral Chinese herbal medicine: 8 weeks/ twice daily (morning & evening)	1) Pain, function 2) Post-treatment
Lin 2019 [39]	1) 40 (20/20) 2) RC injury (clinical and imaging) 3) China	1) Acupotomy (n = 20) versus electrotherapy (n = 20) 2) 2 sessions/ 2 weeks/ once a week 3) Electrotherapy: 14 sessions/ 2 weeks/ once daily	1) Pain, function, proportion of improved participants 2) Post-treatment

Table 4. (Continued).

Study ID (Authory [ref])	1) Sample size 2) Diagnosis 3) Country	1) Interventions and controls 2) Session / duration / frequency of acupuncture treatment 3) Session / duration / frequency of other treatments	1) Primary outcomes 2) Total follow-up periods
Lu, H. 2019 [28]	1) 40 (20/20) 2) Supraspinatus tendinitis (clinical) 3) China	1) EA plus ESWT(n = 20) versus ESWT alone (n = 20) 2) 20 sessions/ 40 days/ once every other day 3) ESWT: 6 sessions/ 6 weeks/ once a week (the next day of EA treatment)	1) Pain, function, proportion of improved participants 2) Post-treatment
Lu, M. 2019 [33]	1) 60 (30/30) 2) RC tear (clinical and imaging) 3) China	1) MA plus manual therapy (n = 30) versus manual therapy alone (n = 30) 2) 15 sessions/ 3 weeks/ 5 times a week 3) Manual therapy: same as those of acupuncture treatment	1) Function, the thickness of bilateral RC tendons, proportion of improved participants 2) Post-treatment
Papadopoulos 2019 [23]	1) 40 (20/20) 2) Supraspinatus calcific tendinitis (clinical and imaging) 3) Greece	1) EA plus oral medications and exercise (n = 20) versus oral medications and exercise alone (n = 20) 2) 6 sessions/ 3 weeks/ 2 sessions per week 3-1) Oral medications: 3 weeks/ not reported 3-2) Exercise: 3 weeks/ 5 times daily	1) Pain, ROM (forward elevation, abduction) 2) Post-treatment
Perez-Palomares 2017 [51]	1) 120 (57/63) 2) RC tendinopathy or subacromial impingement syndrome (clinical and imaging) 3) Spain	1) TrP-DN plus manual therapy (n = 57) versus manual therapy alone (n = 63) 2) 3 sessions/ 5 weeks/ at first, fourth, and seventh sessions among 10 sessions of treatment 3) Manual therapy: 10 sessions/ 5 weeks/ twice a week	1) Pain 2) Up to 3 months post-treatment
Shi 2019 [34]	1) 104 (52/52) 2) RC tear (clinical and imaging) 3) China	1) EA plus manual therapy (n = 52) versus manual therapy alone (n = 52) 2) not reported/ 6 weeks 3) Manual therapy: not reported/ 6 weeks	1) Pain, function, ROM 2) Post-treatment
Sun 2013 [46]	1) 36 (12/12/12) 2) Shoulder impingement syndrome (clinical) 3) China	1) EA plus massage and exercise (n = 12) versus EA plus MW and exercise (n = 12) versus massage, MW and exercise (n = 12) 2) 28 sessions/ 31 days/ once daily, 1 day rest between 7 days of treatment 3-1) Massage: same as those of acupuncture treatment 3-2) MW: same as those of acupuncture treatment 3-3) Exercise: not reported	1) Sub-elements of Constant Murley score: pain, ADL, ROM, strength; proportion of improved participants 2) Mid-/post-treatment
Wan 2017 [40]	1) 150 (50/50/50) 2) RC injury (clinical and imaging) 3) China	1) MA (n = 50) versus MA plus injection therapy (n = 50) versus injection therapy alone (n = 50) 2) not reported/ 20-30 days 3) Injection therapy: 4-5 sessions/ 4-5 weeks/ once a week	1) Function, proportion of improved participants 2) Post-treatment
Wang 2017 [29]	1) 52 (26/26) 2) Supraspinatus tendinitis (clinical and imaging) 3) China	1) Acupotomy (n = 26) versus no treatment (n = 26) 2) 1 session/ 1 day 3) no treatment	1) Strain rate in the therapeutic target of the supraspinatus tendon, pain 2) Up to 12 weeks post-treatment
Wang 2018 [35]	1) 120 (40/40/40) 2) RC tear (clinical and imaging) 3) China	1) EA (n = 40) versus EA plus manual therapy (n = 40) versus manual therapy alone (n = 40) 2) 30 sessions/ 6 weeks/ 5 times per week 3) Manual therapy: same as those of acupuncture treatment	1) Pain, function, ROM 2) Post-treatment
Yang 2019 [47]	1) 150 (75/75) 2) Subacromial impingement syndrome (clinical) 3) China	1) Warm needle acupuncture (n = 75) versus topical NSAID (n = 75) 2) 28 sessions/ 4 weeks/ once daily 3) Topical NSAID: 4 weeks/ 3-4 times daily	1) Pain, function, ROM, proportion of improved participants 2) Post-treatment
Zhang 2015 [30]	1) 76 (19/19/19/19) 2) Supraspinatus tendinitis (clinical) 3) China	1) Fire needle acupuncture (n = 19) versus acupotomy (n = 19) versus fire needle acupuncture plus acupotomy (n = 19) versus oral medication (n = 19) 2-1) Fire needle: 6 sessions/ 2 weeks/ 3 times a week 2-2) Acupotomy: 2 sessions/ 2 weeks/ once a week 3) Oral medication: 2 weeks/ three times a day	1) Pain, function, proportion of improved participants 2) Post-treatment
Zhang 2016 [31]	1) 72 (36/36) 2) Supraspinatus tendinitis (clinical) 3) China	1) Acupotomy plus injection therapy (n = 36) versus injection therapy alone (n = 36) 2) 3 sessions/ 3 weeks/ once a week 3) Injection therapy: same as those of acupuncture treatment	1) Pain, function, proportion of improved participants 2) Up to 3 weeks post-treatment
Zhang 2017 [32]	1) 105 (35/35/35) 2) Supraspinatus tendinitis (clinical) 3) China	1) Acupotomy (n = 35) versus acupotomy plus injection therapy (n = 35) versus injection therapy alone (n = 35) 2) 3 sessions/ 3 weeks/ once a week 3) Injection therapy: same as those of acupuncture treatment	1) Pain, function, proportion of improved participants 2) Up to 3 weeks post-treatment
Zhang 2016 [50]	1) 80 (38/42) 2) Chronic shoulder pain (clinical) 3) China	1) Contralateral MA (n = 38) versus physical therapy (n = 42) 2) 20 sessions/ 4 weeks/ 5 times a week 3) Physical therapy: 4 weeks/ daily exercise (not reported for heat or cold therapy)	1) Pain 2) Up to 16 weeks post-randomization

ADL, activities of daily living; EA, electroacupuncture; ESWT, extracorporeal shock wave therapy; MA, manual acupuncture; MW, microwave; NSAID, non-steroidal anti-inflammatory drug; RC, rotator cuff; ROM, range of motion; TrP-DN, trigger point dry needling; UCLA, University of California-Los Angeles.

Table 5. Effect Size of Reported Secondary Outcomes.

Outcome	No. of studies/ participants	Effect size
Acupuncture versus non-pharmacological interventions		
Pain (intermediate-term) assessed with 100mm VAS	1 study (n = 80) [50]	Favors acupuncture MD −40.9 [95% CI −49.5, −32.3]
Function (intermediate-term) assessed with DASH score	1 study (n = 80) [50]	Favors acupuncture MD −16.1 [95% CI −21.6, −10.6]
AROM (short-term) assessed with degrees of flexion, abduction, and external rotation	1 study (n = 40) [36]	Shows no difference between acupuncture and control or favors control Flexion MD 1.81 [95% CI -2.64, 6.26] External rotation MD 0.97 [95% CI -2.83, 4.77] Abduction MD -11.89 [95% CI -20.15, -3.63]
Acupuncture versus pharmacological interventions		
Function (intermediate-term) assessed with ASES score	1 study (n = 178) [41]	Favors acupuncture MD 15.60 [95% CI 10.34, 20.86]
Proportion of improved participants (intermediate-term)	1 study (n = 67) [49]	Shows no difference between acupuncture and control RR 1.07 [95% CI 0.81, 1.42]
AROM (short-term) assessed with degrees of flexion, abduction, and external rotation	1 study (n = 150) [47]	Favors acupuncture Flexion MD 14.53 [95% CI 10.17, 18.89] Abduction MD 5.49 [95% CI 3.50, 7.48] External rotation MD 4.08 [95% CI 2.40, 5.76]
Acupuncture plus non-pharmacological interventions versus non-pharmacological interventions alone		
Pain (intermediate-term) assessed with NRS and VAS	2 studies (n = 170) [48,51]	Shows no difference between acupuncture and control MD -0.08 [95% CI -1.05, 0.89]
Pain (long-term) assessed with NRS	1 study (n = 50) [48]	Shows no difference between acupuncture and control MD -0.10 [95% CI -0.90, 0.70]
Function (intermediate-term) assessed with DASH score and CMS	2 studies (n = 170) [48,51]	Shows no difference between acupuncture and control MD 1.30 [95% CI -1.14, 3.74]
Function (long-term) assessed with DASH score	1 study (n = 50) [48]	Favors acupuncture MD 1.72 [95% CI 1.06, 2.38]
Proportion of improved participants (long-term)	1 study (n = 47) [48]	Shows no difference between acupuncture and control MD 1.21 [95% CI 0.99, 1.47]
AROM (short-term) assessed with degrees of flexion, abduction, and external rotation	3 studies (n = 344) [34,35,51]	Shows no difference between acupuncture and control Flexion MD 20.60 [95% CI -16.92, 58.12] Abduction MD 9.49 [95% CI -6.98, 25.96]
	2 studies (n = 224) [34,35]	Shows no difference between acupuncture and control External rotation MD 7.51 [95% CI -8.75, 23.76]
AROM (intermediate-term) assessed with degrees of flexion and abduction	1 study (n = 120) [51]	Shows no difference between acupuncture and control Flexion MD -1.76 [95% CI -7.88, 4.36] Abduction MD 1.77 [95% CI -7.33, 10.87]

AROM, active range of motion; VAS, visual analogue scale; NRS, numeric rating scale; CMS, Constant-Murley score; DASH, Disabilities of the Arm, Shoulder and Hand; MD, mean difference; CI, confidence interval; ASES, American Shoulder and Elbow Surgeon.

diclofenac gel combined group was observed in the acupuncture group (2 studies; n = 212; MD -1.29; 95% CI -1.49 to -1.10; I^2 = 0%) [30,47]. Acupuncture was superior to loxoprofen, diclofenac gel, or local corticosteroid injection combined in terms of shoulder function measured using several scales within 12 weeks (4 studies; n = 462; SMD 0.71; 95% CI 0.39 to 1.03; I^2 = 60%) [30,41,43,47]. Acupuncture showed favorable results compared with the loxoprofen, diclofenac gel, or local corticosteroid injection combined in terms of the proportion of improved participants within 12 weeks (6 studies; n = 644; RR 1.17; 95% CI 1.02 to 1.35; I^2 = 76%) [30,41-43,47,49].

Acupuncture plus non-pharmacological interventions versus non-pharmacological interventions alone

Eight studies of acupuncture plus non-pharmacological interventions versus non-pharmacological interventions alone were included in the analysis [28,33-35,37,46,48,51]. Non-pharmacological interventions included in this comparison were manual therapies [33-35,51], exercise [48], ESWT [28], and a combination of the physical therapies (i.e., electrotherapy, exercise, massage [37,46]. Five studies reported pain intensity measured within 12 weeks. One study [48] reported both current pain and the worst shoulder pain experienced in the past week; the current intensity of pain was used for the analysis because the other four studies evaluated the overall pain currently experienced. There was significant reduction of pain with acupuncture treatment than with the manual therapies, exercise, or ESWT combined (5 studies; n = 431; MD -1.53; 95% CI -2.19 to -0.88; I^2 = 90%) [28,34,35,48,51]. All eight studies reported shoulder function within 12 weeks which was measured using several instruments. One study [34] reported both the UCLA shoulder rating scale score and the Shoulder Pain and Disability Index score for the assessment of shoulder function. The UCLA shoulder rating scale was chosen for the analysis, because it was also used in other two studies. The acupuncture group showed favorable results compared with the control group (8 studies; n = 557; SMD 1.74; 95% CI 0.91 to 2.57; I^2 = 94%). Use of the Shoulder Pain and Disability Index score in the study [34] did not change the direction of effect (SMD 1.36; 95% CI 0.80 to 1.92; I^2 = 88%) although the magnitude of effect was diminished. Modest benefits of acupuncture treatment were observed in terms of the proportion of improved participants within 12 weeks compared with ESWT, manual therapy, or physical therapies combined (4 studies; n = 163; RR 1.15; 95% CI 1.03 to 1.28; I^2 = 0%) [28,33,37,46].

Acupuncture plus pharmacological interventions versus pharmacological interventions alone

Pharmacological interventions included in this comparison of acupuncture plus pharmacological interventions versus pharmacological interventions alone were local triamcinolone or procaine injection [31,32,40], oral analgesics and non-steroidal anti-inflammatory drugs [23], and oral Chinese herbal medicine (i.e., Xujin Jiegu liquid; 续筋接骨液) [38]. Of the five relevant studies [23,31,32,38,40], one study [23] could not contribute to the meta-analysis due to missing information on the sample size and the variance of the effects. In the study, the mean VAS score of shoulder pain measured at 3 weeks was 4.6 in the control group and 1.5 in the acupuncture group [23]. There was a modest reduction of pain in the acupuncture group compared with the local triamcinolone or procaine injection or Xujin Jiegu liquid combined group measured within 12 weeks (4 studies; n = 369; MD -0.98; 95% CI -1.94 to -0.01; I^2 = 89%) [31,32,38,40].

Four studies [23,31,32,38] reported shoulder function measurements within 12 weeks. One study [23] which was excluded from the meta-analysis, reported the mean Instrumental Activities of Daily Living score as 6.8 in the control group and as 7.4 in the acupuncture group (a higher score indicates a better outcome). There was a significant benefit of acupuncture compared with the local triamcinolone injection or Xujin Jiegu liquid combined in terms of shoulder function measured within 12 weeks (3 studies; n = 219; SMD 0.84; 95% CI 0.19 to 1.49; I^2 = 80%) [31,32,38]. There was no between-group difference in the proportion of improved participants within 12 weeks compared with local triamcinolone or procaine injection (3 studies; n = 309; RR 1.05; 95% CI 0.94 to 1.16; I^2 = 0%) [31,32,40].

Other analyses

Three subgroup analyses were available, including acupotomy versus non-acupotomy, RCD without tear versus RCD with tear, and manual acupuncture versus EA. There was no evidence against the null hypothesis that the effects of the subgroups were not different. Three sensitivity analyses were conducted, one of which showed a marked but not statistically significant increase in the effect size when the analysis was confined to studies with both clinical and radiological assessments of RCD in the comparison of acupuncture with non-pharmacological interventions (Appendix E.1). The same sensitivity analysis for the comparison of acupuncture plus non-pharmacological interventions with non-pharmacological interventions alone showed an increase in the effect size with statistical significance (Appendix E.3). In a fixed-effect model for short-term pain in a comparison of acupuncture plus non-pharmacological interventions with non-pharmacological interventions alone, the magnitude and precision of the effect estimates were increased compared with random-effects model (Appendix E.2). Assessment of small study effects were unavailable due to the insufficient number of studies.

Safety of interventions

Adverse events of manual acupuncture were reported in one study [27] including headaches (n = 3), dizziness (n = 2), loss of strength in the legs (n = 1), and an inflammatory reaction (n = 1) in the acupuncture group. There were 4 studies with a manual acupuncture group which reported that no adverse events occurred [33,45,49,50]. One study reported itchiness and redness of the skin after fire-needling (n = 6), and dizziness during acupotomy (n = 2) [30]. Four trials which had an acupotomy group reported that no adverse events occurred [31,32,38,43]. One trial with a dry needling group [48], and two trials with EA groups [28,35] reported that no adverse events occurred. One study reported that they had planned to assess adverse events, but did not report the adverse events in the results section [47]. The rest of the studies did not provide safety data.

Grading of Recommendations Assessment, Development and Evaluation approach to assess the certainty of the evidence

The certainty of the evidence for the primary outcome (i.e., pain, shoulder function, and the proportion of improved participants) was determined. The certainty of evidence of acupuncture versus sham acupuncture for short-term shoulder function was downgraded once from high to moderate for imprecision due to the small number of participants. The certainty of evidence of other comparisons downgraded three times from high to very low due to serious concerns on the risk of bias, indirectness, imprecision and/

or inconsistency (Appendix F).

Discussion

Summary of main findings

There were 28 RCTs involving 2216 participants included in this review, that evaluated the effectiveness and safety of acupuncture treatments for RCDs. Most studies compared acupuncture either alone or in combination with active comparators , or with an active comparator alone, implying the current evidence has been focused on evaluating the additive effects or comparative effectiveness of acupuncture compared with other interventions. The certainty of evidence for the primary outcomes in the studies in this review were mostly very low (except for one outcome) due to the high/unclear risk of bias, substantial heterogeneity across studies, imprecision of the estimates, and potential indirectness from different study contexts, which indicated a careful interpretation of the effect estimates in the review. All trials reported short-term outcomes and around a half provided intermediate-term outcomes, which indicated the absence of evidence of acupuncture for long-term results in patients with RCDs. The reported adverse events were minor and not frequent, although incomplete reporting of safety data was prevalent in included studies of this review. Overall, very-low certainty of evidence was observed on the short-term benefits of acupuncture either alone or combined with active comparisons as compared with the same active comparison alone.

Overall completeness and applicability of evidence

The participants in the included trials were patients from outpatient clinics. Most of the trials were conducted and published in China, and the findings of this review may not be applicable in different settings. Clinical characteristics such as availability of radiological confirmation of RCDs, severity and duration of symptoms before the study enrolment, types of acupuncture, and control interventions and outcome measures were heterogeneous. Therefore, the findings of this review provide only rough information on the evidence of acupuncture for RCDs. Non-penetrating types of acupuncture such as laser acupuncture or acupressure were not included in this review, and evaluating evidence requires future studies. As the review does not provide evidence for effects of combination interventions such as acupuncture plus cupping, moxibustion, or herbal medicine, the evidence may have limited application in Korea or some East Asian countries where combinations of treatments are commonly practiced in clinic [54].

Most studies have focused on outcomes in pain, shoulder function, or other symptoms. Therefore, it remains unclear whether acupuncture is beneficial for improving quality of life or other patient-reported outcomes such as satisfaction, which were rarely addressed in the studies of this review. Incompleteness of reporting on safety did not allow a comprehensive assessment of the harmful effects of acupuncture.

Potential biases in the review process

A substantial number of the included RCTs did not report the method of randomization or details of allocation concealment. Despite best efforts to obtain further information on details of random allocation process, this was not possible (absence of the e-mail address or response). Therefore, risk caused by including non-randomized trials cannot be excluded in this review which may have biased the review results towards the overestimation of the effects. The risk of attrition bias was rated as low when the number of participants enrolled and those analyzed were same, although intention-to-treat analyses could not be guaranteed. This may have biased results in this review, although the direction of bias on the effect estimates seems unclear. The proportion of improved participants was analyzed as a primary outcome because it was frequently reported in the Chinese trials included in this review, and was deemed as an important outcome, although it was not pre-defined at the protocol stage. This ad-hoc analysis may have potentially introduced the risk of chance findings. Therefore, the results should be interpreted with caution. Pooled effect estimates were sought regardless of the heterogeneity, against the study protocol and the standard guidance [14]. This was because the pooled effect estimates may have provided exploratory information for further research, although the considerable heterogeneity, and risk of bias should be considered when interpreting the pooled effects. The existence of small study effects could not be assessed due to insufficient number of the studies in the same meta-analysis. Therefore, it remains unclear whether publication bias affected our findings.

Agreements and disagreements with other studies or reviews

One systematic review of acupuncture for RCD was identified [11], along with four systematic reviews related to acupuncture for shoulder pain [7-10]. The search date and range of databases searched were different between studies. Few or none of the Chinese studies were analyzed in the previous reviews. This review reflected studies with a wide range of acupuncture-related interventions. The eligibility criteria was similar in one review [11], but it excluded studies that administered analgesics as co-interventions, whereas this current review did not set any limitations on the co-interventions other than acupoint-related interventions. Similarities between the findings of this current review and previous reviews include high/unclear risk of bias in the included studies, paucity of longer-term outcome assessment and of patient-relevant outcomes including quality of life and patients' satisfaction, and incomplete reporting on safety of acupuncture, which may indicate little progress in the quality of methodology in trials on this topic over the years.

Implications for practice

Based on the overall very low-certainty of the evidence, observed short-term benefits of acupuncture should be interpreted with caution. Incompleteness of reporting on safety of acupuncture should be considered, especially for interventions with potentially higher risks such as acupotomy or warm/fire needle acupuncture. Whether acupuncture can yield a long-term improvement in the symptoms or shoulder function of patients with RCDs remains unclear. Any particular types of acupuncture or regimens of interventions cannot be endorsed from this current review, although details of acupuncture treatments might be referred to as a source of information for clinical practice.

Implications for research

High-quality RCTs with adequate power to give meaningful results, and in various settings should be conducted in the future. Transparent reporting of the methods and results are required for valid interpretation of study findings. Bias associated with the randomization process, outcome assessor blinding, incomplete outcome reporting, selective outcome reporting, and misclassification due to absence of radiological assessment of RCDs

should be addressed in designing future trials. Evidence on the role of acupuncture for long-term recovery, quality of life, and patients' satisfaction is needed. Use of validated and standardized outcomes across studies may enable meta-analysis of the data, which would enable the examination of small study effects. Information on safety of interventions should be explicitly reported.

Conclusion

Overall, very low-certainty evidence for the short-term benefit of acupuncture alone, or acupuncture combined with other active treatments was observed compared with other active treatments in terms of the pain, shoulder function, and the proportion of improved participants. The reported benefits should be interpreted with great caution because of the methodological limitations, incomplete reporting, and considerable heterogeneity of the studies included in the meta-analyses.

Supplementary Materials

Appendix data are available at https://www.e-jar.org.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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