

Efficacy and safety of warm needle treatment for scapulohumeral periarthritis

A protocol for systematic review and meta-analysis

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Abstract

Background: To evaluate the effectiveness and safety of warm needle acupuncture (WNA) treatment for Scapulohumeral periarthritis.

Methods: Relevant randomized controlled trials will be searched from the databases of Pubmed, the Cochrane Library, Embase, CNKI, Wanfang Database, CBM and VIP Database from their inception to September 2021. The primary outcomes are effective rate, visual analog scale score. The secondary outcomes are Constant-Murley score, Japanese Orthopaedic Association scores, adverse events. Two reviewers will independently select studies, collect data, and assess the methodology quality by the Cochrane risk of bias tool. The Stata 14.0 will be used for meta-analysis.

Results: This study is ongoing and will be submitted to a peer-reviewed journal for publication.

Conclusion: This study will provide an assessment of the current state of WNA for the scapulohumeral periarthritis, aiming to show the efficacy and safety of WNA treatment.

Ethics and dissemination: There is no requirement of ethical approval and informed consent, and it will be in print or published by electronic copies.

Registration: INPLASY2020100049

Abbreviations: PRISMA-P = Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols, RCTs = randomized controlled trials, SP = scapulohumeral periarthritis, WNA = warm needle acupuncture.

Keywords: meta-analysis, protocol, scapulohumeral periarthritis, systematic review, warm needle acupuncture

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Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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1. Introduction

1.1. Description of the condition

Scapulohumeral periarthritis (SP) is a chronic, sterile, specific inflammatory reaction caused by injury or degeneration of the joint capsule around the shoulder joint and its surrounding ligaments, tendons, bursae, muscles and other soft tissues.^[1–3] The incidence of SP has been reported to be 2% to 5% in some studies,^[4,5] and 5% to 8.79% in China,^[6] with a higher incidence in women than in men (about 3:1) and is characterized by slow onset and long duration of disease,^[7] with a high incidence at the age of 40 to 70 years old and around 50 years old,^[8] with more women than men,^[9] bringing tremendous benefits to patients' daily life and work. The pain, especially at night, affects sleep and can lead to depression or anxiety in the long run.^[10–12] Shoulder pain and limitation of movement affects all aspects of a person's life, suggesting that treatment of this condition is essential.

The current treatment of SP is mainly conservative, with non-surgical treatment consisting of oral non-steroidal medications, intra-articular injections of tretinoin, bupivacaine suprascapular nerve blocks.^[13,14] Although shoulder pain and joint motion improve in the short term, most of the effects disappear within 4 weeks after treatment.^[15,16] Besides, joint cavity injections may

result in serious adverse events such as infectious arthritis and cartilage damage.^[17]

1.2. Description of the intervention

Warm Needle Acupuncture (WNA) is an important part of Traditional Chinese Medicine acupuncture therapy in which the acupuncturist adds a warm stimulus, such as a burning moxa stick, to the needle handle to deliver heat and needle sensation to the deeper tissues, thereby enhancing the therapeutic effect.^[18] It combines the technical advantages of acupuncture and moxibustion to produce better therapeutic results and is a safe and effective treatment without any toxic side effects.^[19] Evidence from relevant studies shows that WNA can effectively relieve chronic pain,^[20] such as lumbar disc herniation,^[21] rheumatoid arthritis,^[22] can strengthen the immune system,^[23] improve blood circulation,^[24] and help in the treatment and recovery of chronic pain conditions.

To our knowledge, a large number of studies have shown that WNA has a significant effect on the improvement of pain and shoulder function in SP patients.^[25] However, the relationship between WNA and SP has not been elucidated. Therefore, our aim in this review was to conduct a systematic review and meta-analysis to assess the effectiveness and safety of WNA for the SP.

2. Methods and analysis

2.1. Study registration

The protocol has been registered on the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY) registration number, INPLASY2020100049 (<https://inplasy.com/inplasy-2020-10-0049/>) basing on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement guidelines.^[26]

2.2. Study eligibility criteria

2.2.1. Type of studies. All randomized controlled trials evaluate the effectiveness and safety of WNA in the treatment of SP will be included. There is no uniform requirement for the language of the survey results.

2.2.2. Type of participants. Patients diagnosed with SP are not restricted by age, sex, race, occupation, education, aetiology, and severity etc. The diagnostic criteria must be clear.

2.2.3. Type of interventions. The purpose of the study is on clinical trials of WNA for the SP. WNA, or WNA combine with other conventional treatments were used as the intervention measures in the treatment group, while the control group was given conventional treatments such as drugs, placebo, sham acupuncture and no treatment, and so on.

2.2.4. Types of outcome measures

2.2.4.1. Primary outcome. The primary outcomes are effective rate, visual analog scale score.

2.2.4.2. Secondary outcomes.

- (1) Constant-Murley score,
- (2) Japanese Orthopaedic Association scores,
- (3) Adverse events caused by WNA, such as scald, vomiting, weariness, dizziness, nausea, so on.

2.3. Search strategy

We will search for Pubmed, the Cochrane Library, Embase, CNKI, Wanfang Database, CBM and VIP Database from its inception to September 2021 with a language restriction on Chinese or English. The search adopts a combination of subject terms and free words, and the search strategy is determined after multiple pre-searches. We search the retrieval type are “warm needle acupuncture” or “needle warming moxibustion” and “Scapulohumeral periarthritis” Table 1 summarizes Pubmed preliminary search strategy, which will be adjusted according to the grammatical requirements of other electronic databases.

This search strategy will be modified as required for other electronic databases.

2.4. Identification of studies

Endnote X9 will be used for study selection. Two evaluators (WXY and HXH) conducted independent literature screening and cross-cutting. First, duplicate literature was excluded. For duplicate literature, the most comprehensive literature was selected. Then, the title and abstract were read to exclude obviously irrelevant literature. Finally, the full text was read to determine the final systematic review. To ensure the consistency of the literature screening, please cross-check the screening results

Table 1

Search strategy used in PubMed database.

Number	Search terms
#1	“scapulohumeral periarthritis”[MeSH Terms] OR “frozen shoulder”[MeSH Terms] OR “adhesive periarthritis of shoulder”[MeSH Terms] OR “periarthritis of shoulder”[MeSH Terms]
#2	“scapulohumeral periarthritis”[Title/Abstract] OR “frozen shoulder ”[Title/Abstract] OR “adhesive periarthritis of shoulder”[Title/Abstract] OR “periarthritis of shoulder”[Title/Abstract] OR “shoulder pain”[Title/Abstract] OR “Shoulder osteodystrophy”[Title/Abstract] OR “Shoulder osteoarthritis”[Title/Abstract] OR “Shoulder Periarthritis”[Title/Abstract] OR “Shoulder Pains”[Title/Abstract]
#3	#1 OR #2
#4	“warm needle acupuncture”[MeSH Terms] OR “warming acupuncture”[MeSH Terms] OR “needle warming moxibustion”[MeSH Terms]
#5	“warm needle acupuncture”[Title/Abstract] OR “warming acupuncture”[Title/Abstract] OR “needle warming moxibustion”[Title/Abstract] OR “needle warming moxibustion”[Title/Abstract] OR “needle warming”[Title/Abstract]
#6	#4 OR #5
#7	(“randomized controlled trial”[Publication Type] OR “controlled clinical trial”[Publication Type] OR “randomized”[Title/Abstract] OR “placebo”[Title/Abstract] OR “clinical trials as topic”[MeSH Terms] OR “randomly”[Title/Abstract] OR “trial”[Title]) NOT (“animals”[MeSH Terms] NOT “humans”[MeSH Terms])
#8	#3 AND #6 AND #7

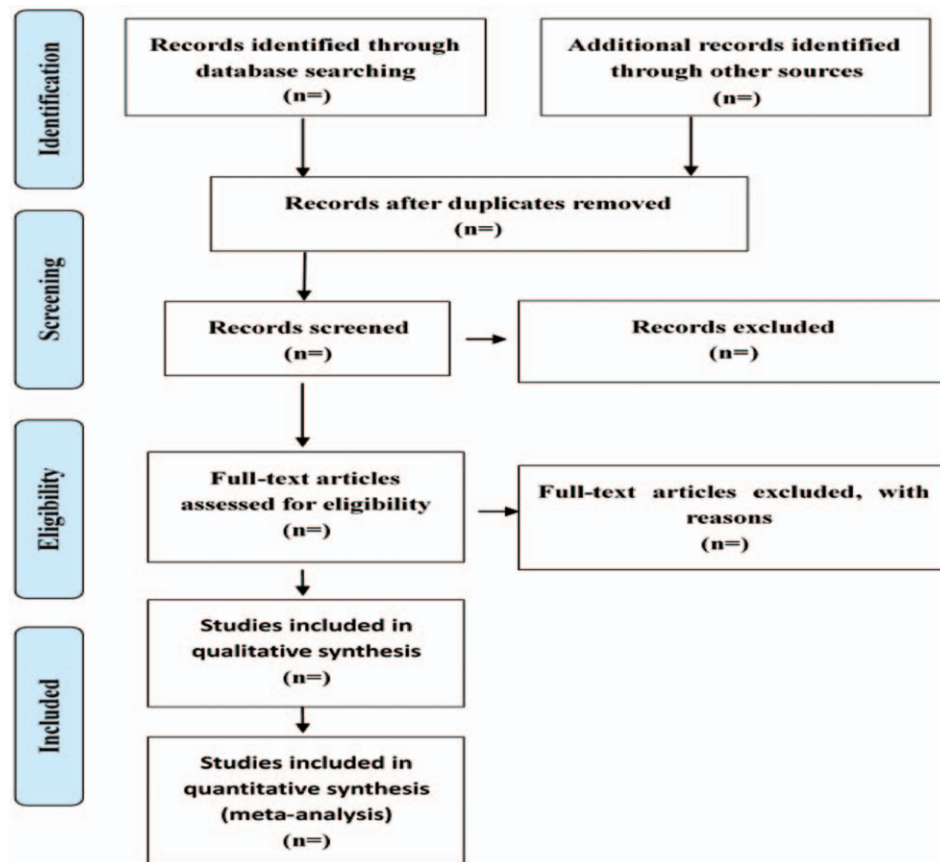


Figure 1. Flow diagram of studies identified.

and resolve any differences through discussion or negotiation with the third evaluator (JDL and YLJ). The details of the selection process are shown in Figure 1

2.5. Data collection

The two evaluators (WXY and HXH) conducted independent data extraction based on a predetermined data extraction table, and then cross-discussed to resolve any differences, or negotiated with the third evaluator (WQ and XGQ) to decide whether there was a difference. The following information and data were extracted from each included clinical trial: authors, time of publication, randomization method, blinding, number of cases of observation, diagnostic criteria, interventions and controls, duration of treatment, outcome measures (effective rate, visual analog scale score, Constant-Murley score, Japanese Orthopaedic Association scores, adverse events), and follow-up.

2.6. Risk of bias assessment

The quality of the included literature was assessed by 2 evaluators (WXY and LHN) using the risk of bias assessment tool recommended in the Cochrane Handbook 5.3,^[27] and if disagreements arose they were resolved by discussion or a third evaluator (LF and WQ) was consulted for a decision. Criteria included: correct use of randomisation; correct use of allocation concealment; correct use of blinding of patients; correct use of

blinding of researchers; completeness of results and data; selective reporting of results; and presence of relevant bias. The standard for assessing the risk of bias adopts 3 levels of “low risk of bias,” “high risk of bias,” and “unclear risk of bias.”^[28]

2.7. Statistical analyses

Meta-analysis was performed using RevMan 5.3 software. Relative risk and 95% confidence interval were used for the count data, standardized mean difference and 95% confidence interval were used for the measurement data as effect measures; if there was heterogeneity among the intervention protocols included in the studies, the heterogeneity test was performed between the studies using the karyotype test (test for $\alpha = 0.05$), when $P < 0.1$ or $I^2 > 50\%$. perceived heterogeneity, using random-effects should model to calculate the risk ratio of the overall result; conversely, the fixed-effects model was used to calculate, and publication bias was analyzed using funnel plots. Subgroup analyses were performed based on factors that could be heterogeneous, and sensitivity analyses were performed when heterogeneity originated from low-quality studies.^[29]

2.8. Analysis of subgroups or subsets

If the included studies are highly heterogeneous, we will perform a subgroup analysis based on age, sample size, methodological quality, and so on.

2.9. Sensitivity analysis

If heterogeneity is significant, we will conduct a sensitivity analysis to assess the robustness and quality of the findings by excluding each included study individually and varying the study's impact scale.

2.10. Ethics and dissemination

As the relevant data we extracted does not involve any personal privacy, we will not apply for ethical approval. We will publish this study to assess the validity and safety of WNA for SP and present it in a peer-reviewed journal or at a conference.

2.11. Summary of evidence

We will evaluate the quality of the evidence and classify it on 4 levels according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) guidelines: high, moderate, low or very low.^[30]

3. Discussion

SP is a condition of limited shoulder movement, the severity of which can range from mild pain and/or mild limitation of movement to severe pain and/or severe limitation of movement, characterized by gradual onset of shoulder stiffness, severe pain (especially at night) and limited active and passive range of motion, and the main intervention is currently conservative treatment. Acupuncture is increasingly accepted by clinicians and patients in the treatment of musculoskeletal pain.^[31] In recent years, acupuncture and moxibustion have been widely used as a safe and non-obvious treatment for SP. Studies have shown that WNA can regulate the overall condition of the human body and is beneficial to analgesia.^[32] Besides, WNA is very safe to operate on heating and stimulating acupoints, with almost no side effects. This study conducted a systematic review and meta-analysis of the effectiveness and safety of WNA for the SP, and provided references for WNA treatment of SP. Besides, the agreement will also provide WNA clinical outcome indicators, treatment effects, adverse reactions and side effects.

The protocol has been developed under the PRISMA-P and is registered with the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY). It will follow the guidelines of the Cochrane Handbook of Systematic Intervention Reviews and the PRISMA-P statement.

Author contributions

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