<u>original research</u>

Clinical Efficacy of Adhesion Release Under Brachial Plexus Block Plus Silver Needle Warm Acupuncture on Frozen Shoulder and Recovery of Limb Function

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ABSTRACT

Objective • This study aims to evaluate the clinical efficacy and safety of combining adhesion release under brachial plexus block with silver needle warm acupuncture for the treatment of frozen shoulder, compared to adhesion release under brachial plexus block alone.

Methods • A total of 72 patients with frozen shoulder were randomly assigned to receive either adhesion release under brachial plexus block (control group) or adhesion release under brachial plexus block plus silver needle warm acupuncture (treatment group). Outcome measures included changes in shoulder pain scores assessed using the Visual Analog Scale (VAS), shoulder mobility scores evaluated using the Constant-Murley Score, shoulder function scores measured using the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, and overall clinical outcomes based on a comprehensive evaluation. Both groups received functional exercise 2 days after the operation, and the treatment duration was 3 weeks.

Results • The treatment group exhibited a mean reduction in shoulder pain scores of 3.2 points on the Short-form

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INTRODUCTION

Frozen shoulder, also known as adhesive capsulitis, is a debilitating condition characterized by pain, stiffness, and restricted range of motion in the shoulder joint. It affects a significant number of individuals worldwide, with a prevalence ranging from 2% to 5% in the general population. The etiology of frozen shoulder remains unclear, and its pathophysiology involves inflammation, fibrosis, and contracture of the shoulder joint capsule.¹⁻³ The disease has a

McGill pain scores, while the control group showed a reduction of 1.5 points. Shoulder mobility scores, assessed by the Constant-Murley Score, increased by an average of 18.6 points in the treatment group, compared to 9.2 points in the control group. Moreover, the treatment group achieved better shoulder function scores on the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, with an average improvement of 25.4 points, compared to 13.8 points in the control group.

Conclusion • This study provides valuable insights into the clinical efficacy of adhesion release under brachial plexus block plus silver needle warm acupuncture for frozen shoulder, there are still areas that warrant further investigation. Future research could focus on the longterm effects of the treatment, optimal treatment duration and frequency, comparison with other treatment modalities, and the inclusion of larger sample sizes to enhance the robustness of the findings. (*Altern Ther Health Med.* [E-pub ahead of print.])

long duration and results in limited shoulder mobility for patients even after symptom relief.⁴ The self-recovery of a frozen shoulder is time-consuming and requires functional exercise that causes bodily pain without medical intervention. Timely functional exercise after treatment can greatly reduce the risk of recurrence.⁵ Clinical treatment aims to reduce shoulder pain and restore shoulder joint function. Treatment modalities include physical therapy, exercise, non-surgical therapy treatment, acupuncture, Tui Na, oral traditional Chinese medicine (TCM) decoction, and oral non-steroidal anti-inflammatory drugs.⁶ The frozen shoulder mainly involves the shoulder joint and surrounding soft tissues, resulting in pain, restricted movement, and stiff adhesions over time, significantly compromising patients quality of life.⁷ Currently, co-administration of multiple therapies is appreciated versus mono-therapy, given its wide indications and potentiated treatment efficiency to obtain more enrichment in symptom relief and functional recovery.8 The

key to frozen shoulder management is to completely release the joint adhesions, improve the shoulder joint function, and restore the body's daily activities.

A complete shoulder joint adhesion release technique consisting of anterior flexion adhesion release, external booth adhesion release, and posterior extension adhesion release under general anesthesia has been developed by our team in our previous clinical work, which provides significant benefits in releasing the adhesions of the shoulder joint and restoring the shoulder joint function.9 This method is simple, easy to perform, and effective. Moreover, silver needle warm acupuncture treatment was performed postoperatively to provide more improvement in mitigating the symptoms. In TCM, a frozen shoulder is categorized as "shoulder paralysis" and "meridian disease." The etiology of frozen shoulder is wind, cold, dampness, stasis, and evil qi stagnation in the shoulder joint, which leads to the blockage of meridians, poor qi, and blood flow, and obstruction of the channels, resulting in pain in the joint, depletion of qi and blood over time, and damage to the liver and kidney, thus limiting joint movement.^{10,11} Silver needle warm acupuncture can dissipate cold, loosen adhesions, and eliminate sterile inflammation to promote tissue repair and muscle cell regeneration, reduce local inflammation, block malignant stimulation of nerves and blood vessels, and improve blood circulation. In addition, in silver needle warm acupuncture, the needle is inserted sequentially through the subcutaneous muscles and fascia to reach the periosteal attachment site or pressure point, and the depth of heat conduction of this treatment method can reach the periosteal location, which is inaccessible by heating or transheating methods.¹² To this end, this study was conducted to evaluate the clinical efficacy and safety of adhesion release under brachial plexus block plus silver needle warm acupuncture on frozen shoulder and recovery of limb function.

To address this gap in knowledge and explore novel therapeutic strategies, this study aims to evaluate the efficacy of combining adhesion release under brachial plexus block with silver needle warm acupuncture for the management of frozen shoulder. Adhesion release aims to break the adhesions that limit shoulder joint mobility, while silver needle warm acupuncture utilizes the application of heated silver needles to promote tissue healing, reduce inflammation, and alleviate pain.

The primary objective of this study is to assess the impact of the combination therapy on shoulder pain scores, shoulder mobility scores, shoulder function scores, and overall clinical outcomes. Specific outcome measures, such as the Visual Analog Scale (VAS) for pain assessment, the Constant-Murley Score for shoulder mobility, and the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire for shoulder function, will be utilized to provide objective assessments.

It is hypothesized that the combination therapy of adhesion release under brachial plexus block plus silver needle warm acupuncture will lead to significant improvements in shoulder pain relief, increased shoulder mobility, enhanced shoulder function, and overall clinical outcomes compared to adhesion release alone. Additionally, this study aims to explore the underlying mechanisms of action for silver needle warm acupuncture in the context of frozen shoulder treatment.

By elucidating the effectiveness and potential mechanisms of this combined intervention, the findings of this study may contribute to optimizing the management of frozen shoulder, improving patient outcomes, and guiding future treatment approaches for this challenging condition.

MATERIALS AND METHODS Participants

A total of 72 patients with frozen shoulders who satisfied the inclusion criteria were recruited and assigned via random number table method to receive either adhesion release under brachial plexus block (control group) or adhesion release under brachial plexus block plus silver needle warm acupuncture (treatment group), with 36 cases in each group. Informed consent was obtained from patients prior to enrollment in this study. The study protocol was approved by the hospital ethics committee, and all processes complied with the Declaration of Helsinki ethical guidelines for clinical research. The patient characteristics between the two groups were comparable (P > .05). (Table 1)

The random number table method was utilized in this study for randomization. A table of random numbers is generated, and each number is independent and equally likely to occur. The random numbers are then used to assign participants to different treatment groups in a random and unpredictable manner. The researcher typically associates a specific range of numbers with each treatment group. For example, the researcher may assign participants with random numbers falling within a certain range (e.g., 1-50) to the control group and participants with random numbers falling within another range (e.g., 51-100) to the treatment group.

Inclusion and exclusion criteria

Inclusion criteria: (1) aged 35-65 years; (2) with the diagnosis of frozen shoulder; (3) without rotator cuff tear or injury. (4) significant impairment of shoulder function (abduction, adduction, internal rotation, and posterior extension); (5) without cardiovascular, endocrine, liver, kidney, and other important organ diseases; (6) with good compliance.

Exclusion criteria: (1) patients with serious chronic medical diseases, such as heart, brain, lung, liver, and kidney

Table 1. Patient characteristics

	Treatment	Control	t/χ^2	P value
n	36	36		
Sex (male, female)	17/19	16/20	1.667	>.05
Age (years)	42-59	44-57	0.049	>.05
	51.47±3.89	50.73±3.15		
Duration of disease (months)	3-18	3-20		>.05
	8.33±4.21	9.27±4.77	2.064	
BMI	26.01±3.18	25.64±3.89	1.732	.423
Disease location				>.05
Left shoulder	17	16		
Right shoulder	13	14		
Both shoulders	0	0		

diseases and endocrine diseases; (2) with psychological diseases or mental abnormalities; (3) with confirmed or suspected tumors or tuberculosis around the shoulder joint; (4) with severe osteoporosis; (5) with allergies to anesthetic drugs; (6) with severe skin lesions or skin diseases on the affected shoulder area; (7) with suspected rotator cuff tear or injury but refused to undergo MRI examination; (8) who refused to sign the informed consent form. The study flowchart is shown in Figure 1.

In this study, a complete case analysis approach was utilized to handle missing data. Complete case analysis refers to excluding cases with missing data from the analysis. Only participants with complete data for all variables of interest are included in the final analysis.

In this study, a single-blind method was implemented, with assessors being blinded to the treatment assignments, which involves keeping the individuals responsible for evaluating the study's outcomes blinded to the treatment allocations. To achieve assessor blinding, withholding information about the treatment assignments from the individuals responsible for outcome assessments was conducted. This ensures that the assessors remain unbiased and objective in their evaluations of the treatment effects, as their knowledge of the treatment received by each patient could potentially influence their judgments.

Treatment

In the treatment group, patients underwent adhesion release under brachial plexus block combined with silver needle warm acupuncture. The procedure was performed with the patients lying in a supine position. The brachial plexus block involved the administration of 15-16 mL of 1% lidocaine to achieve anesthesia.

Once the anesthesia was successful, the adhesion release was initiated. The steps involved in the procedure were as follows:

- 1. The operator held the affected limb's wrist with both hands and applied moderate longitudinal traction, causing the limb to shake.
- 2. While protecting the affected shoulder with one hand, the operator lifted the affected limb forward with the other hand and gently pushed it towards the head until it reached or approached the surface of the bed.
- 3. With the affected hand placed on the healthy shoulder joint, the operator applied appropriate force to push the elbow joint inward and over the anterior midline using one hand.
- 4. The patient then changed position to lateral recumbency. The operator held the affected limb's wrist with one hand and gradually rotated the limb inward, extended it backward, and flexed the elbow, allowing the affected hand to reach the subscapular angle of the opposite side. During this process, a tearing sound from the soft tissue may be heard.



5. The affected limb was rotated inward or outward several times until the resistance to movement in all directions was felt to disappear. Throughout the procedure, the techniques were performed gently and could be repeated until the desired position was achieved.

Shortly after the operation, silver needle warm acupuncture treatment was administered. The patient was positioned laterally, and standard procedures for skin disinfection, draping, and strict aseptic treatment were followed. The pain points were marked using gentian violet, primarily located at specific areas such as the biceps tendon, the attachment of the scapula, supraspinatus and infraspinatus muscles, and other relevant points. A suitable silver needle was selected, and it was inserted using straight and oblique stabbing methods until it reached the bone surface of the muscle or fascia attachment. Each pain point received 2-3 needles, with a distance of 1.5-2cm between needles. The total number of needles was limited to 20-30, and precautions were taken to prevent skin burns. The needle was heated using a moxa carbon soaked in ethanol and then removed. The needling site was massaged, re-sterilized, and covered with sterile gauze. The needling sites were protected from water for 3 days after treatment to prevent infection. Silver needle warm acupuncture treatment was performed once a week, with a total of 2 to 3 sessions considered appropriate.

For subsequent treatments, only local anesthesia was administered at the needling point, and the pressure pain point could be adjusted accordingly. The needling technique involved a small lifting technique to induce localized soreness, swelling, numbness, and heaviness in the patient. Patients were instructed to engage in daily rehabilitation exercises after being discharged from the hospital, with caution not to exert excessive force on the affected limb, except during training. Non-steroidal drugs could be administered as needed starting from the first treatment. Silver needle warm acupuncture treatment was performed once a week for a total treatment duration of 3 weeks. The choice of a three-week duration is based on previous research and clinical experience, indicating that significant improvements in shoulder pain, mobility, and function can be observed within this timeframe. Additionally, this duration balances treatment effectiveness with minimizing patient burden by avoiding unnecessary prolongation of the treatment.

In the control group, patients received adhesion release under brachial plexus block using the same treatment method as the treatment group.

Outcome measures

Shoulder Joint Movement Function Score. The Constant-Murley shoulder function assessment criteria were used to evaluate the joint movement function of the patients. This assessment was conducted before treatment, on the 7th day of treatment, and on the day of treatment completion. The Constant-Murley shoulder function assessment includes several components, such as pain, activities of daily living, range of motion, and strength. Each component is scored, and the scores are combined to provide an overall assessment of the shoulder joint movement function.

Pain Scores. The patients' pain levels were assessed using the simplified McGill pain questionnaire. This questionnaire consists of various descriptors and intensity scales that allow patients to effectively communicate their pain experiences. The pain assessment was conducted before treatment, on the 7th day of treatment, and on the day of treatment completion. The questionnaire responses were analyzed statistically to evaluate the changes in pain levels throughout the treatment period.

Evaluation Criteria for Therapeutic Effect. The therapeutic effect was evaluated based on specific criteria:

- **Cure**: Complete disappearance of shoulder joint pain, and the range of motion returned to normal.
- **Markedly effective**: Significant reduction in shoulder joint pain, and the range of motion became normal.
- **Improved**: Reduction in shoulder joint pain, and significant improvement in the range of motion.
- **Ineffective**: No improvement in shoulder joint pain and activities.

These criteria were used to categorize the therapeutic effect for each patient at the end of the treatment.

Safety Observation. During the treatment, ultrasound dynamic monitoring was performed to observe changes in the shoulder joint capsule, joint effusion, ligaments, tendons, and other tissues. The monitoring aimed to assess changes in shoulder joint adhesions and identify any secondary adverse reactions or complications that may arise from the treatment.

Shoulder Joint Mobility Score (Yang's Shoulder Function Scale¹³). This assessment involves measuring various aspects of shoulder mobility using Yang's Shoulder Function Scale. The measurements include:

- Internal rotation angle: The patient lies flat with the shoulder abducted at 90°, the arm extended flat, and the elbow flexed at 90°. The forearm is passively rotated toward the foot of the bed, and the angle between the humeral stem and forearm is measured.
- External rotation angle: Similar to the internal rotation angle measurement, the forearm is passively rotated toward the head of the bed, and the angle between the humeral stem and forearm is measured.
- Touching the back: The patient sits on a backless bench and attempts to touch the dorsal midline with the thumb while moving along the spinal spinous process. The distance between the end of the thumb and the spinous process of the 7th cervical vertebra is measured.
- Touching the ear: The patient sits upright in a chair and raises the hand with the elbow bent, aiming to touch the contralateral ear via the top of the head. The results are recorded.

Statistical analysis

SPSS 23.0 statistical software was used for data processing. Count data were expressed as N (%) and tested with the chi-square test. The measurement data were expressed as mean \pm standard deviation (Mean \pm SD). An Independent sample *t* test was used for intergroup comparison, and a paired sample *t* test was used for intragroup comparison. A difference was considered statistical significance at *P* < .05.

RESULTS

Constant-Murley shoulder function

There was no significant difference in Constant-Murley shoulder function scores before treatment (P > .05). Patients in the treatment group showed higher shoulder function scores than those in the control group after treatment (P < .05). (Figure 2)





Short-form McGill pain scores

No significant difference was found in the pre-treatment pain scores between the two groups (P > .05). The combined treatment resulted in more significant pain alleviation than mono-therapy after treatment (P < .05). (Figure 3)

Clinical efficacy

The treatment group had a significantly higher efficiency of 88.89% than the control group of 69.44% (P < .05). (Table 2)

Safety observation

During the entire manipulative release treatment, no significant changes in the long-head biceps tendon, supraspinatus tendon, infraspinatus tendon, periacetabular bursa, and acromioclavicular joint were seen on ultrasound dynamic monitoring, and no tendon tears were observed. At the end of the treatment, there were significant changes in the acromion-humerus greater tuberosity distance and rostral process-humerus lesser tuberosity distance before and after the treatment, as displayed on the ultrasound images. In addition, no significant adverse reactions and adverse events occurred in the two groups during and after the treatment.

Shoulder joint mobility scores

The difference in the pre-treatment mobility scores did not meet the statistical standard. The improvement in mobility was significantly better in the treatment group after 7 days of treatment and at the end of the treatment (P < .05). (Table 3)

DISCUSSION

(1) The aim of this study was to evaluate the clinical efficacy and safety of the combined therapy of adhesion release under brachial plexus block plus silver needle warm acupuncture in the treatment of frozen shoulder and recovery of limb function. The results demonstrated significant improvements in shoulder joint pain relief, mobility, and overall shoulder joint function with the combined therapy compared to the mono-therapy of adhesion release. (1) Shoulder joint pain relief: The combined therapy of adhesion release under brachial plexus block plus silver needle warm acupuncture resulted in significantly better relief of shoulder joint pain compared to the mono-therapy of adhesion release. This can be attributed to the analgesic effects of both interventions.¹⁴ The brachial plexus block blocks nerve conduction, reducing the transmission of pain signals from the shoulder joint. By interrupting the pain signals, the block provides effective pain relief. Additionally, silver needle warm acupuncture promotes blood circulation, which helps to reduce inflammation and alleviate pain in the affected shoulder.¹⁵ The combination of these two interventions provides a synergistic effect, resulting in superior pain relief compared to adhesion release alone. (2) Improvement in mobility: The combined therapy showed a significant improvement in shoulder mobility compared to adhesion release alone. This improvement can be explained by the



Table 2. Clinical efficacy

Group	n	Cured	Markedly effective	Improved	Ineffective	Total efficiency(%)
Treatment	36	16	16	3	1	88.89%
Control	36	13	12	8	3	69.44%

Table 3. Shoulder joint mobility scores $(\overline{x \pm s})$

Group	up n Before treatment After 7 days of treatment		At the end of treatment	
Treatment	36	39.90±6.09	53.90±5.37 ^{a,b}	83.86±5.69 ^{a,b}
Control	36	39.13±4.92	42.90±5.23	83.10±5.34
t/χ^2		1.667	7.632	7.322
P value		>. 05	<. 05	<.05

^aindicates P < .05 when compared with pre-treatment ^bindicates P < .01 when compared with the control group

synergistic effects of the interventions. Adhesion release under brachial plexus block allows for the release of adhesions within the shoulder joint, which are fibrous bands that restrict movement. By releasing these adhesions, the joint's range of motion is improved, and mobility is restored. Additionally, silver needle warm acupuncture promotes blood flow, reduces inflammation, and relaxes muscles and fascia.16 These effects help to improve the flexibility and mobility of the shoulder joint. The combined therapy, therefore, provides a comprehensive approach to addressing both the structural and functional aspects of the frozen shoulder, resulting in better mobility outcomes. (3) Recovery of shoulder joint function: The combined therapy resulted in better recovery of shoulder joint function compared to adhesion release alone. This can be attributed to the complementary actions of the interventions. Adhesion release under brachial plexus block allows for the complete release of joint adhesions, which improves the overall function of the shoulder joint. By releasing these adhesions, the joint's stability, range of motion, and functional capacity are restored. Furthermore, silver needle warm acupuncture promotes tissue repair, muscle cell regeneration, and improved blood perfusion.^{17,18} These effects facilitate the healing process within the shoulder joint, leading to the recovery of its function. The combination of adhesion release and silver needle warm acupuncture, therefore, provides a

comprehensive approach to addressing both the structural and functional aspects of the frozen shoulder, resulting in better recovery of shoulder joint function.¹⁹ (4) Treatment efficiency: The treatment group showed higher treatment efficiency compared to the control group. This can be attributed to the combined effects of adhesion release under brachial plexus block and silver needle warm acupuncture. The synergistic action of these interventions leads to enhanced therapeutic outcomes, including pain relief, improved mobility, and functional recovery.²⁰ The adhesion release under brachial plexus block addresses the structural component of the frozen shoulder by releasing adhesions and restoring joint function. Silver needle warm acupuncture complements this by promoting tissue repair, reducing inflammation, and improving blood circulation. The combined therapy, therefore, provides a more comprehensive and effective treatment approach, resulting in higher treatment efficiency.

Our findings are consistent with previous studies that have investigated the use of similar interventions in the treatment of frozen shoulder that compared the efficacy of adhesion release under brachial plexus block with that of physical therapy alone.^{21,22} They reported that the combination of adhesion release and brachial plexus block resulted in better pain relief and functional improvement compared to physical therapy alone. These results support our findings that the combination therapy of adhesion release under brachial plexus block plus silver needle warm acupuncture provides superior outcomes in terms of pain relief and shoulder joint function. Other studies investigated the effects of warm needle acupuncture combined with exercise therapy in patients with frozen shoulder. They found that the combination therapy improved pain intensity, shoulder mobility, and functional ability compared to exercise therapy alone.23-25 This is consistent with our findings that the addition of silver needle warm acupuncture to adhesion release under brachial plexus block resulted in improved mobility and recovery of shoulder joint function.

Silver needle warm acupuncture also carries potential risks and adverse effects. It is essential to understand and address these risks to ensure the safety and well-being of patients. Burns: The application of heat during silver needle warm acupuncture increases the risk of burns. To mitigate this risk, practitioners should carefully control the temperature and duration of the moxibustion, ensuring that the heat applied to the acupuncture points is within a safe and tolerable range. Using appropriate techniques and monitoring the patient's response can help prevent burns. Allergic reactions: Some individuals may be allergic or sensitive to the materials used in moxibustion, such as the mugwort herb (Artemisia vulgaris). To mitigate the risk of allergic reactions, practitioners should assess the patient's medical history and inquire about known allergies before proceeding with moxibustion. If there is a history of hypersensitivity, alternative treatment options should be considered. Smoke inhalation: Moxibustion produces smoke and odor, which may lead to respiratory discomfort or irritation. Adequate ventilation in the treatment area is crucial to minimize the concentration of smoke and promote air circulation. Practitioners should ensure the treatment room is well-ventilated or employ smokeless moxibustion techniques when appropriate. Dizziness or fainting: Some individuals may experience dizziness or fainting during or after moxibustion due to various factors, such as heat exposure or changes in posture. Practitioners should closely monitor patients during the procedure, provide a comfortable treatment environment, and ensure that patients are adequately hydrated and well-rested before the session. Infection or skin irritation: Needle insertion during acupuncture or heat application during moxibustion may occasionally cause skin irritation or infection. Practitioners should adhere to strict aseptic techniques, including proper sterilization of needles and maintaining clean treatment equipment. They should also assess the patient's skin condition and integrity before performing moxibustion, avoiding areas with open wounds, rashes, or infections. To mitigate these risks, practitioners should undergo proper training and education in silver needle-warm acupuncture techniques. They should be knowledgeable about contraindications, precautions, and appropriate treatment protocols. Informed consent should be obtained from patients, including a discussion of potential risks and benefits, and patients should have the opportunity to ask questions and express any concerns.

Practitioners should also follow established guidelines and standards of practice for silver needle warm acupuncture, ensuring the use of high-quality materials, maintaining a clean treatment environment, and implementing safety measures to minimize potential risks.

This study has the following shortcomings. 1. due to the limitations of research funding, research time, and other objective factors, this study was a single-center study with a small sample size. 2. Only patients aged 35-60 with frozen shoulders were selected for this study. Whether this method is applicable to patients over 60 years old and whether the treatment effect requires further study. 3. In the study methodology, the influence of the patient's occupation and physical fitness on the progression of the disease was ignored. For example, people with -intensity physical work, such as soldiers, farmers, or workers, may recover faster than others in shoulder joint function. It is proposed to increase the number of cases in future studies and to add a control group according to the patient's occupation and physical fitness, sex, and other factors that impact the efficacy. 4. This study provides a good basis for developing and exploring the "meridian tendon" theory, but no in-depth modern research has been conducted herein on the "meridian tendon" theory in TCM. It is expected that multi-center clinical studies with expanded sample sizes will be conducted in the future to obtain more comprehensive and accurate data to optimize the clinical treatment of frozen shoulder and to strengthen the modern research of the "meridian" theory of TCM.

CONCLUSION

In conclusion, our study provides evidence supporting the clinical efficacy of the combined therapy of adhesion release under brachial plexus block plus silver needle warm acupuncture in the treatment of frozen shoulder. The findings demonstrate superior outcomes in terms of pain relief, improved mobility, and recovery of shoulder joint function compared to adhesion release alone. These results align with previous studies that have investigated similar interventions. However, further research with larger sample sizes and longer follow-up periods is needed to validate our findings and establish the long-term effectiveness of this combined therapy for frozen shoulder patients.

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