Journal of Pain Research

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STUDY PROTOCOL

Thread-Embedding Acupuncture for the Treatment of Shoulder Instability: Protocol for a Randomized, Controlled, Patient-Assessor Blinded Pilot Study

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Purpose: This study aims to determine the feasibility of thread-embedding acupuncture (TEA) for the treatment of shoulder instability.

Patients and Methods: This is a patient-assessor blinded, randomized, sham-controlled trial with two parallel arms. A total of 40 patients with shoulder instability aged between 13 and 43 years will be recruited and screened using set inclusion and exclusion criteria. After screening, they will be randomly allocated to the TEA or sham TEA group. Patients in both groups will then receive TEA or sham TEA treatment on six acupoints once a week for 8 weeks, which will be followed by additional follow-up assessments at 4 and 8 weeks after the end of treatment. Changes in shoulder pain and disability will be assessed as the primary outcome, whereas 100-mm pain visual analogue scale, shoulder range of motion, rotator cuff quality of life index, EuroQol 5-dimension 5-levels, treatment satisfaction, economic evaluation, and safety will all be measured as secondary outcomes of the study. Outcome assessment will be conducted at baseline and at 4, 8, and 16 weeks after screening.

Conclusion: The results from this trial will help to design further clinical trials on the efficacy, safety, and cost-effectiveness of performing TEA for shoulder instability.

Trial Registration Number: KCT0005921 (Clinical Research Information Service of the Republic of Korea).

Keywords: thread-embedding acupuncture, shoulder instability, shoulder pain, pilot study, randomized controlled trial

Introduction

The shoulder joint is surrounded by various ligaments and the rotator cuff muscles, all of which maintain shoulder stability through constant tension and contraction. As such, shoulder instability is a condition of frequent humeral head subluxation and dislocation due to hyperlaxity of the shoulder joint.[1,2]

In the general population, the incidence rate of shoulder instability in the United States and Europe has been reported to range from 0.08 to 0.24 dislocations per 1000 person-years in previous studies.[3–5] Particularly, in the US military, this incidence rate was relatively high at 1.69 dislocations per 1000 person-years, and young age and males were found to be high risk factors.[6] Collision sports have also been highly associated with shoulder instability, showing a high recurrence rate among athletes in this field of sports.[7,8]

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Received: 14 July 2021
Accepted: 26 August 2021
Published: 4 September 2021

Treatment of shoulder instability includes administration of anti-inflammatory medications, corticosteroid injections, physical therapy, and surgery. Among these treatment modalities, physical therapy is commonly preferred for elderly and bedridden patients, whereas surgery is recommended when patients have traumatic instability or a highly active lifestyle, or when patients have continued symptoms for more than 6 months despite physical therapy.[9] Regardless of what treatment is used, it is necessary to develop an effective treatment regimen, since shoulder instability has a long course that can greatly affect quality of life.[10]

Thread-embedding acupuncture (TEA) is a novel type of acupuncture that offers the effects of needle acupuncture with long-term stimulation, which is produced by an embedded medical thread. This embedded thread is administered for the purpose of prolonging the same therapeutic effect of conventional needle acupuncture, such as analgesic effect,[11] and experimental studies have shown that embedded thread can promote fibrous cell regeneration in connective tissue through experimental studies.[12–14]

In the past, catgut was mainly used in TEA, but recently, the safety and durability of the thread have been improved with the use of surgical materials, such as polydioxanone sutures. Based on these improvements in safety, TEA has been used for the treatment of a wide range of diseases including obesity, rhinitis, facial paralysis,[15] and several conditions of musculoskeletal pain.[16–19]

Furthermore, for the purposes of long-term pain management and functional improvement, many studies on TEA treatment for shoulder diseases have shown considerable clinical effects for frozen shoulder,[20] periarthritis,[21] and rotator cuff syndrome;[22] however, there has been no clinical study on the effect of TEA on shoulder instability.

Therefore, the feasibility of TEA for shoulder instability treatment will be identified through this pilot trial including a small sample size by evaluating its efficacy, safety, and cost-effectiveness, as compared to a sham-control group.

Patients and Methods

Trial Design

This study is a randomized, patient-assessor blinded, sham-controlled trial with two parallel groups. A total of 40 participants with shoulder instability will be allocated to the TEA group and sham TEA (STEA) group in a 1:1 ratio.

This trial will be conducted in accordance with the Declaration of Helsinki. The study protocol has been approved by the Institutional Review Board (IRB) (KHNMCOH 2020–11-004), and has been registered with the Clinical Research Information Service of the Republic of Korea (Registration number: KCT0005921). All research procedures will comply with the Korean Good Clinical Practice (KGCP) guidelines. The methodological details of TEA were established in accordance with the revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines.[23] The items of the protocol refer to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[24]

Participants

Participants fulfilling the following inclusion criteria will be included in this study: (1) aged between 18–43 years for both sexes; (2) having a severity of pain during activity (daily activity or light exercise) that is greater than 30 and lesser than 70 on a 100-mm pain visual analogue scale (VAS); (3) having radiological evidence of humeral head subluxation on stress view; (4) having a visually observed instability on physical examination via Apprehension and Drawer tests; (5) having correspondence with involuntary shoulder instability; (6) capable of communicating sufficiently with the researcher and completing the questionnaire; (7) having pledged to only take the prescribed treatment during the study period; and (8) agreeing to participate after providing a written informed consent.

On the other hand, participants who will meet any of the following exclusion criteria will be excluded from this study: (1) having a severity of pain at rest that is greater than 70 on a 100-mm pain VAS; (2) having correspondence with voluntary shoulder instability; (3) having a history of shoulder surgery; (4) having radiological evidence of fracture, osteoarthritis, or calcific tendinitis; (5) having a systemic pathology, including inflammatory joint disease or neoplastic disorder; (6) having a radiculopathy from spinal disorders related to the cervical spine; (7) having received intraarticular steroid injections in the previous 3 months; (8) having received anti-inflammatory drugs in the previous 2 weeks; (9) having a diagnosis of mental illness that impedes compliance with clinical tests; (10) having musculoskeletal disorders that may affect efficacy assessment, or any joint disease that makes it impossible for the individuals to participate in the clinical trial; and (11) being judged by the researchers to be ineligible to participate in the clinical trial.

Procedure

A total of 40 participants with shoulder instability will be recruited at the Kyung Hee University Hospital at

Gangdong. The recruited participants will be given detailed information regarding the study, and only those who participate voluntarily will be included in the study. Those who will agree to participate and sign the informed consent form will be screened for eligibility, and if they fulfill the inclusion and exclusion criteria, the participants will be randomly allocated to the TEA or STEA group. Following random allocation, eight treatment sessions for 8 weeks and two follow-up sessions for an additional 8 weeks will be conducted, according to the 16-week appointed schedule (Table 1).

Interventions

In both groups, the intervention will be administered once a week for eight weeks using a 29-gauge, 40-mm TEA or STEA needle (Hyundae Meditech, Wonju, South Korea) on six acupoints selected by experts.

TEA Group

The TEA procedure will be performed on the acupoints located in the muscles related with shoulder stability. Specifically, transverse embedding will be used for the supraspinatus, infraspinatus, and deltoid muscles, whereas perpendicular embedding will be used for the teres minor muscle.

For the supraspinatus muscle, two transverse embeddings will be performed from the LI16 to the SI12 direction and from the SI12 to the SI13 direction. For the infraspinatus muscle, two transverse embeddings will be performed from the SI11 to the SI10 direction, and from the SI11 to the SI12 direction. For the deltoid muscle, one transverse embedding will be performed from the middle point between LI15 and TE14 to the center of the deltoid. Lastly, for the teres minor muscle, one perpendicular embedding will be performed on the SI9. Further details of the treatment group intervention are described in the STRICTA checklist (Table 2).

STEA Group

All procedures and equipment used in the STEA group, including the number of treatments, acupoints, and TEA needle sizes, will be the same as those used in the TEA group. However, the medical thread will be removed prior

Table 1 Planned Schedule of the Trial

Study Period		**Screening**	**Intervention**					**Follow Up**	
Visit		**0**	**1**	**2–3**	**4**	**5–7**	**8**	**9**	**10**
Time point (Week)		**−2 ~ 0**	**1**	**2–3**	**4**	**5–7**	**8**	**12**	**16**
Informed consent		•							
Eligibility screening		•							
Allocation		•							
Intervention			•	•	•	•	•		
Efficacy assessments	SPADI		•		•		•		•
	100-mm Pain VAS	•	•		•		•		•
	Shoulder ROM		•		•		•		•
	RC-QoL		•		•		•		•
	EQ-5D-5L		•		•		•		•
	Treatment satisfaction						•		•
Safety assessments	Vital signs	•	•	•	•	•	•		•
	Laboratory tests	•					•		
	Adverse events		•	•	•	•	•	•	•
Economic evaluation							•		•
Blinding assessment									•

Abbreviations: SPADI, shoulder pain and disability index; VAS, visual analogue scale; ROM, range of motion; RC-QoL, rotator cuff quality of life index; EQ-5D-5L, EuroQol 5-dimension 5-level.

Table 2 Details of the TEA Treatment Listed in Accordance with the STRICTA 2010 Checklist

Item	Detail
1. Acupuncture rationale	1a. Style of acupuncture: TEA
	1b. Reasoning for treatment provided: By the consensus of a group of clinical experts and literature evidence supporting the usefulness of TEA for shoulder disorders.
	1c. Extent to which treatment was varied: No variation.
2. Details of needling	2a. Number of needle insertions per subject per session: Six
	2b and 2c. Names of points used and depth of insertion, based on a specified unit of measurement, or on a particular tissue level: 1) transverse insertion once on LI16 advancing toward SI12, SI12 advancing toward SI13, SI11 advancing toward SI10, SI11 advancing toward SI12, and middle point of LI15 and TE14 advancing toward the center of the deltoid muscle 2) perpendicular insertion once on SI9
	2d. Response sought: De qi
	2e. Needle stimulation: Thread embedding
	2f. Needle retention time: No retention time
	2g. Needle type: TEA (29G × 40 mm; Hyundae Meditech, Wonju, Korea)
3. Treatment regimen	3a. Number of treatment sessions: Eight
	3b. Frequency and duration of treatment sessions: Once a week for 8 weeks
4. Other components of treatment	4a. Details of other interventions administered to the acupuncture group: All other interventions for shoulder pain, including moxibustion, cupping, electronic acupuncture, administration of herbal medicine, and exercise programs, are not allowed during the 8-week treatment phase.
	4b. Setting and context of treatment, including instructions to practitioners, and information and explanations to patients: Minimal conversations between practitioner and participant
5. Practitioner background	5. Description of participating acupuncturists: Licensed acupuncture and moxibustion specialists
6. Control or comparator interventions	6a. Rationale for the control or comparator in the context of the research question, with sources that justify this choice: Threadless needle will be used as comparator. This will ensure that the efficacy observed is specific to the use of thread.
	6b. Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used: All procedures in the control group and experimental groups, including treatment period, number of treatments, acupoints and size of needle, will be the same. However, TEA without thread will be performed for the control group instead of conventional TEA.

Abbreviations: STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture; TEA, thread-embedding acupuncture.

to the STEA group procedure, which will be performed aseptically and discreetly to prevent infection and for participant-blinding, respectively.

Primary Outcome Measure

Shoulder-related pain and dysfunction will be assessed using the shoulder pain and disability index (SPADI) at Visit 1 (baseline), 4, 8 (end of treatment), and 10 (follow-up). The SPADI consists of items divided into two subscales, with five items for pain and eight items for disability. These items are checked on a 10-point Likert scale, with 0 indicating "no pain" or "no difficulty" and 10 indicating the "worst imaginable pain" or "so difficult it required help". In total, the SPADI score will be calculated out of 100, wherein higher scores indicate more pain/disability in a patient.

Secondary Outcome Measures

100-mm Pain VAS

The intensity of shoulder pain will be assessed by determining changes in the 100-mm VAS pain scores at Visit 1

(baseline), 4, 8 (end of treatment), and 10 (follow-up). Patients will self-report their pain intensity from a scale of 0 to 100, with 0 indicating "a painless state" and 100 indicating "the most excruciating pain imaginable," during the past 24 hours (at night, at rest, during exercise).

Shoulder Range of Motion (ROM)

Active and passive shoulder ROM on both sides will be examined in four motions: forward flexion (range: 0°–180°), abduction (range: 0°–180°), external rotation at the side (range" 0°–70°), and internal rotation to the posterior. Shoulder ROM will be measured using a goniometer at Visit 1 (baseline), 4, 8 (end of treatment), and 10 (follow-up).

Rotator Cuff Quality of Life Index (RC-QoL)

The RC-QoL was developed for the use of patients with rotator cuff disorders. The questionnaire consists of 34 questions and five subscales comprising the following: (1) symptoms and physical complaints (16 items); (2) work-related concerns (4 items); (3) recreational activities, sports participation, or competition concerns (4 items); (4) lifestyle concerns (5 items); and (5) social and emotional concerns (5 items). Similarly, these items are checked on a 100-mm VAS from 0 to 100, with 0 indicating "the most excruciating pain or discomfort" and 100 indicating "no pain or discomfort," and the scores will be calculated and averaged.[25] RC-QoL will be administered at Visits 1 (baseline), 4, 8 (end of treatment), and 10 (follow-up).

EuroQol 5-Dimension 5-Level (EQ-5D-5L)

The general health state of the participants will be assessed using the Korean version of the EQ-5D-5L, which is a 20-cm scale ranging from 0 to 100, with 0 indicating the "worst health condition imaginable: and 100 indicating the "best health condition imaginable". The EQ-5D-5L consists of five questions on morbidity, personal care, daily activities, pain/discomfort, and anxiety/depression, and each question is rated from 1 to 5 (1, no problems; 2, slight problems; 3, moderate problems; 4, severe problems; 5, extreme problems). The EQ-5D-5L will be administered at Visit 1 (baseline), 4, 8 (end of treatment), and 10 (follow-up).

Evaluation of Treatment Satisfaction

Treatment satisfaction will be assessed with three questions rated on a 10-point scale at Visit 8 (end of treatment) and 10 (follow-up). Specifically, participants will be asked regarding their (1) satisfaction with the treatment, (2) intention for additional treatment in the future, and (3) intention to recommend the treatment to other people, scoring each question from 1 (very unsatisfied) to 10 (very satisfied).

Economic Evaluation

Treatment cost-effectiveness will be analyzed using structured questions through trial-based economic evaluation at Visit 8 (end of treatment) and 10 (follow-up). In addition to direct medical expenses related to the treatment, the participant's expenses of time, transportation, and nursing will be estimated together from a social point of view.

Safety Outcomes

At Visit 0 (screening) and 8 (end of treatment), the following blood chemistries will be assessed: erythrocyte sedimentation rate, C-reactive protein levels, blood urea nitrogen, creatinine, alanine transferase, and alanine aminotransferase. Moreover, a pregnancy test will be performed using a urine strip kit at Visit 0 (screening) and vital signs (blood pressure, pulse, and body temperature) will be checked at each visit from pre-trial screening to Visit 10 (follow-up), with the exception of Visit 9.

Information regarding expected adverse events (AEs), including temporary symptoms, such as localized bruises, pain, swelling, and foreign body sensation, and serious symptoms suggestive of infection, such as pus, fever, and severe pain, will be provided to the participants along with the informed consent form prior to the pre-trial screening. An AE is defined as an undesirable and unintended sign, symptom, or disease that occurs in a participant receiving an intervention used in a clinical trial. During the study period, the researchers will check for any AEs reported by the participant at each visit, and they will record the name of the AE, date of onset, end date, severity, and its relevance to the treatment in the case report form (CRF). If AEs do occur, the researchers will provide proper examination and treatment to the affected participant in accordance with the compensation rules.

Sample Size

This trial is a preliminary pilot study for an advanced clinical trial. A total of 40 people will be recruited in a 1:1 ratio (20 people will be assigned to each group).

Randomization and Allocation Concealment

A total of 40 participants will be randomly assigned to the TEA or STEA group after block randomization with a 1:1 ratio and a block size of four. Random numbers will then

be generated by an independent statistician using the SAS software (SAS Institute INC., Cary, NC, USA), and random codes will be sealed in sequentially numbered opaque envelopes that will be managed by a clinical research coordinator (CRC). After screening for trial participation confirmation, the CRC will open the envelope and assign the participant to the allocated group according to a random code. Information regarding the allocation will be recorded in a separate log, and its access will only be provided to the researchers who will perform the intervention.

Blinding

This clinical trial is designed as a patient-assessor blinded study. Patient-assessor blinding will be conducted, since TEA cannot be performed with a blinded practitioner. Practitioners will also be prohibited from providing information regarding TEA or STEA treatment to the participants. Both the treatment and control groups will be treated with the same TEA protocol; however, in the STEA group, the medical thread will be removed prior to the treatment. Moreover, efficacy assessment will be performed by an independent assessor who will not participate in the random allocation or treatment. The assessor will inquire about the contents of the assessment and CRF, as well as record the responses in detail, but they will not know about the type of treatment the participants received. Furthermore, the participants, assessors, statisticians, and all related researchers will be blinded to the patient allocation, which will be maintained until the end of the trial.

To assess whether patient-blinding has been successfully achieved, a blinding test will be conducted for the participants in the TEA and STEA groups at Visit 10 (after the end of the study). In this assessment, the assessor will ask the participants what group they think they belonged to, and the participants will respond with one of the following answers: TEA, STEA, or I do not know.

Statistical Methods

An independent statistician will perform statistical analysis using the PASW Statistics 18.0 software, with a statistical significance set at $P<0.05$. In this study, both intention-to-treat and per-protocol analyses will be conducted.

The primary outcome measure of this study will be the mean change in the average SPADI scores at baseline and at 8 weeks. To validate the significant changes between the groups, changes in the SPADI scores will be expressed as means ± standard deviations, and independent *t*-tests will be performed for the comparisons between the groups. Trends over time and time-by-treatment interactions will also be analyzed using repeated-measures analysis of variance. For the secondary outcome analysis, changes in VAS pain scores, ROM, RC-QoL scores, and EQ-5D-5L scores will all be analyzed in the same manner as that for the primary outcome analysis.

For economic evaluation, SPADI and RC-QoL will be used as the primary and secondary effectiveness variables for cost-effectiveness analysis. Net incremental health benefits will be calculated by the difference of the mean change between both groups, and net incremental costs will be estimated using the ingredient method. Finally, the incremental cost-effectiveness ratio will be derived to show the economic value of the additional effect versus the additional costs, and a cost-effectiveness acceptability curve will be presented showing how the probability of cost-effectiveness changes as the social willingness-to-pay for unit effect changes.

Data Collection and Management

Data collection will be performed in accordance with the standard operation protocol of the IRB, and the quality of the study will be managed by the clinical research associate or independent contract research organization. Monitoring will include the compliance assessment of the recruitment and intervention procedures with the protocol and evaluation of the consistency between the records in the CRF and the original document. The monitoring process will also include the management and reporting of AEs that may occur during this trial. All sensitive information obtained from the trial will be secured and discarded after a certain period, and all researchers will be given training in data privacy and protection.

Quality Control

For the quality control of the intervention, TEA treatment will be limited to one licensed acupuncture specialist. Moreover, both groups of participants will be treated in the same environment, and conversations with the practitioner will be minimized, with the exception for essential matters, in order to maintain the quality of blinding. Furthermore, to maintain adequate quality of the trial, the study procedure and documents will be periodically monitored in accordance with the KGCP guidelines.

Discussion

This pilot trial is designed to investigate the clinical effects, safety, and cost-effectiveness of TEA in patients with shoulder instability. Among the therapeutic components of TEA, the hypothesis on the difference in clinical effect depending on the presence of the embedded thread will be tested using a sham-control, in which the thread is removed.

TEA is differentiated from the conventional needle acupuncture in that the thread is embedded in the body following needle insertion and removal. Previous studies have shown that the embedded thread, which is gradually absorbed into the body, causes a long-term therapeutic effect through mechanical and chemical stimulation at the treatment site.[26] In this trial, a STEA needle without the thread will be set as the control intervention, with reference to previous studies[22,27,28] to confirm only the effect of the embedded thread, excluding the stimulation effect of needle insertion. Additionally, to confirm the long-term maintenance effect, 8 weeks of follow-up assessment will be conducted after the end of treatment sessions.

Shoulder instability can be classified based on the direction of displacement, such as anterior, posterior, and multidirectional instability, or according to the cause of displacement, including traumatic or atraumatic instability. Among them, traumatic anterior instability is the most common type, accounting for more than 90% of reported cases, which usually affects young men under 30 years of age, with a peak incidence population associated with collision or overuse due to sports activities.[29,30] In contrast, women have a peak incidence at the age of 80–90 years due to pre-existing degenerative weakening of the muscle around the glenohumeral joint.[31,32]

Therefore, the goal of conservative treatment is to restore shoulder stability by strengthening the muscles related with the dynamic stability of the glenohumeral joint, including the rotator cuff, biceps brachii, and deltoid muscles.[33] However, current conservative treatment often fails, especially among young patients and athletes. As a result, surgical treatment has increasingly been recommended to patients who have high risk of recurrence and are willing to continue playing sports.[34]

In this trial, the feasibility of TEA as a novel conservative treatment candidate for shoulder instability will be tested. Notably, the analgesic effect, mechanism of acupuncture, and improvement of muscle function have been well established in many studies.[35–38] However, since these effects are limited in duration after needle removal, TEA has been attempted as an alternative for diseases requiring long-term management. Furthermore, TEA has been reported to promote connective tissue repair by activating fibroblasts in experimental studies.[12] Thus, it is necessary to confirm whether this mechanism can improve the shoulder laxity, thereby confirming the feasibility of TEA for shoulder instability treatment.

To comprehensively confirm the feasibility of applying TEA to shoulder instability, this protocol also includes various outcome measures, including pain, function, disease-specific quality of life, general quality of life, as well as analysis of safety and economic feasibility.

Conclusion

This study will be significant as it will be the first randomized controlled trial to comprehensively investigate the efficacy, safety, and cost-effectiveness of TEA to treat shoulder instability. The results from this pilot study will be helpful in providing the reference data of TEA feasibility for further confirmative clinical trials.

Abbreviations

AE, adverse event; CRC, clinical research coordinator; CRF, case report form; EQ-5D-5L, EuroQol 5-dimension 5-level; IRB, institutional review board; KGCP, Korean Good Clinical Practice; RC-QoL, rotator cuff quality of life index; ROM, range of motion; SPADI, shoulder pain and disability index; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; STEA, sham thread-embedding acupuncture; STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture; TEA, thread-embedding acupuncture; VAS, visual analog scale.

Ethics Approval and Informed Consent

The study protocol has been approved by the IRB (approval number: KHNMCOH 2020-11-004), and written informed consent form is to be completed voluntarily before screening.

Author Contributions

All authors made a significant contribution to the work reported, whether it was in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to

which the article has been submitted; and have agreed to be accountable for all aspects of the work.

Funding

This study was supported by the Traditional Korean Medicine R&D program, which is funded by the Ministry of Health & Welfare through the Korea Health Industry Development Institute (KHIDI) (HF20C0014).

Disclosure

The authors report no conflicts of interest in this work.

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