

The Role of Acupuncture with Electrostimulation in the Frozen Shoulder

Yu-Te Lee

A. Aim

To evaluate the efficacy of acupuncture with electrostimulation in conjunction with physical therapy in improving mobility and decreasing pain in people with the frozen shoulder.

B. Background

Frozen shoulder is a term used synonymously with adhesive capsulitis in describing an insidious condition which presents with shoulder pain associated with limitation in the range of motion. This was initially described by Duplay in 1872 when he discussed the difference between a painful shoulder stiffness and arthritis. In 1934, Codman coined the phrase "frozen shoulder" in describing a painful limitation in the range of motion of the shoulder joint. In 1946, Neviasser gave the term "adhesive capsulitis" based on arthrographic finding of decreased capsular volume in this condition. Frozen shoulder is a fairly common diagnosis among the patients presenting with shoulder pain, but its etiology has yet to be determined. Biopsies of the shoulder capsule reveal only an increase in fibrous tissue, fibroblasts, and vascularity with little inflammatory infiltrates. Four stages of pathologic development have been described: 1) early fibrinous synovial reaction; 2) adhesive synovitis; 3) loss of axillary fold; 4) restrictive adhesions. The condition is seen more commonly in the diabetic population and has some association with myocardial infarction and shoulder surgery. However, the predominant proportion of patients are otherwise healthy, with usually no history of trauma. The condition is seen more commonly in women than men, usually in the 4th to 6th decades of life, and is self-limited in course, although lasting years before the resolution of pain and return of full range of motion. Three clinical phases have been described: 1) pain predominantly in the glenohumeral joint; 2) shoulder stiffness with limitation in all shoulder joint movements; 3) gradual return to normal function. Therapy consists mainly of physical therapy, with manipulation under local or general anesthesia reserved for non-responders. Recovery is generally slow, with patients requiring at least 2 to 3 months of physical therapy before achieving functional ADL's, and up to a year before return to normal function.

This study will evaluate the efficacy of acupuncture with electrostimulation in conjunction with physical therapy in accelerating the achievement of ADL's. As pain is a significant hurdle in performing effective ROM exercises, the well-described role of acupuncture in pain relief, especially with electrostimulation, should provide significant benefit to this patient population.

C. Hypothesis

Acupuncture with electrostimulation in conjunction with physical therapy will decrease the amount of time necessary to achieve functional ADL's in patients afflicted with the frozen shoulder.

D. Methods

a. Patient Selection

Patients between the age of 40-70 will be recruited from the general medicine and orthopedic clinics who presented with shoulder pain. Careful history, physical exam and plain roentgenograms will be performed to rule out recent trauma, fracture, dislocation, or referred pain from pulmonary, diaphragmatic and cardiac etiologies. Patients with diabetes will be excluded as they tend not to respond

to physical therapy. Subjects with cardiovascular disease will also be excluded due to the possible use of electrostimulation. Subsequent evaluation by the orthopedist will be required, with intra-articular steroid/lidocaine injection, for a clinical diagnosis of frozen shoulder. By definition, this is a condition producing passive and active restriction in shoulder movements despite achieving analgesia with intra-articular injection. We will look to recruit 50 patients, 25 in each arm, who are willing to undergo the possibility of acupuncture therapy. To be included in the study, they must meet the two criterias: 1) maximum passive range of motion not exceeding 110 degrees abduction, and 2) not exceeding 140 degrees flexion. Members of the research team will approach the potential candidates, explain the study, and obtain informed consent.

b. Study Location

Physical therapy and measurements of shoulder ROM will be performed in the outpatient Vanderbilt Clinic, and acupuncture will be performed in the office of the certified, licensed acupuncturist.

c. Study Protocol

The 50 research subjects will be randomized into the two arms of the study, physical therapy only, and acupuncture with electrostimulation prior to physical therapy. All subjects will be asked at the beginning of the study their beliefs in the efficacy of acupuncture and any prior experiences. Physical therapy will consist of passive and active range of motion movements to enhance mobility of the shoulder joint, as well as strength exercises as per the Neer Protocol. Heat and ultrasound massage modalities may be used as per the therapist as deemed necessary in the rehabilitation of the shoulder. Sessions will be done three times a week, lasting approximately 30 minutes each, for the duration of time deemed necessary by the therapist. The therapist will be blinded to the arm that the patient has been randomized.

Subjects in the acupuncture arm will receive, prior to the physical therapy session, acupuncture with a 2.0 inches needle in six locations (LI 11 -Quchi, LI 14-Binao, LI 15 Jianyu, SI 10-Naoshu, TB 14-Jianliao, M-UE 48- Jianneiling)*. The ends of the needles will be attached to a direct current 9-volt power unit with the electric current increased to the point that a sense of fullness, heaviness, or mild degree of muscle spasm is elicited. Each session will last twenty minutes, with three sessions per week, prior to the physical therapy visit. One course of acupuncture will be a total of 10 sessions. Subjects will undergo two courses of therapy, if needed, with three days rest in between.

Objective measurements of the degree of passive and active mobility of the affected shoulder in abduction and flexion will be performed with a goniometer prior to the PT regimen on the initial and last visits of the week. Measurements will be taken with the patient seated, arm initially at side, palm toward body. Arm is raised in the frontal plane and rotated such that the palm faces forward during abduction. At the point of limitation both active and passive, the goniometer is positioned with its axis over the anterior surface of the acromion, stationary arm aligned parallel to the midline of the body and moving arm aligned parallel to the midline of the humerus. Similar measurements will be taken with the palm pronated and the arm in flexion. Patient will also be requested to fill out a visual analogue scale describing the intensity of their pain, and record the ADL's that they are able to accomplish. A two month follow-up will be performed to determine the rates of relapse.

E. Analyses

A chi-squared analysis of the successes of each arm after one month of therapy, defined as achieving complete functional ADL's, will be made. We will examine if acupuncture produced significantly more subjects who are able to perform ADL's independently. The sequential changes in the degrees of range of motion will be plotted and linear regression will be performed. Analysis of covariance will be used to analyze the significance of the changes achieved in each subject after one month of therapy.

F. Safety

Physical therapy is a therapeutic modality for the condition of frozen shoulder and carries no risk in experienced hands. Acupuncture with electrostimulation involves needle puncture and electric stimulation. Morbidity from the needle puncture is minimal, with complications of small hematomas and rare cases of broken needle tips being reported.

Medical therapy will be provided as needed. Electrical stimulation is with a small voltage and no harm is expected, especially as patients with cardiovascular disease will be excluded.

G. Benefits

The subjects will be receiving physical therapy as per routine treatment for the frozen shoulder. Those subjects undergoing acupuncture will possibly benefit from accelerated improvement in symptoms and decrease in pain.

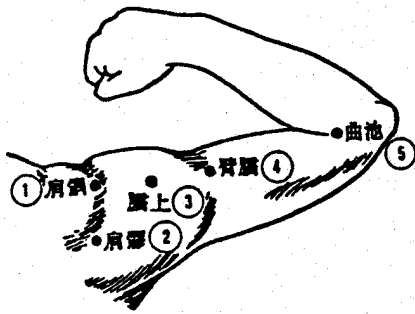
H. Expected Findings

We expect to find a significant increase in the shoulder mobility of the acupuncture subjects, and thereby a dramatic decrease in the time needed to achieve functional ADL's.

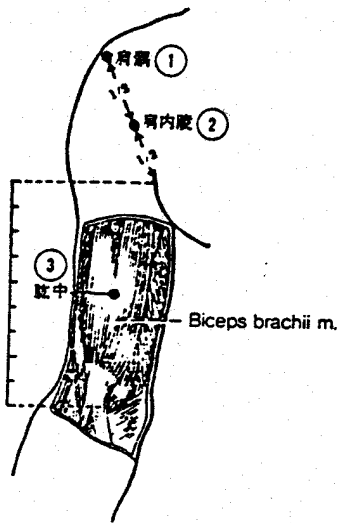
I. Significance

Reduction in the amount of time necessary to achieve functional ADL's will be beneficial in lowering the medical expenses and time lost from work.

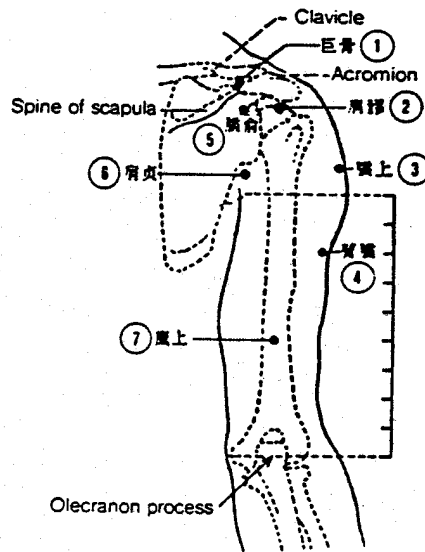
*



- ① LI-15 (*Jianyu*)
- ② TB-14 (*Jianliao*)
- ③ N-UE-14 (*Naoshang*)
- ④ LI-14 (*Binao*)
- ⑤ LI-11 (*Quchi*)



- ① LI-15 (*Jianyu*)
- ② M-UE-48 (*Jianneiling*)
- ③ N-UE-9 (*Gongzhong*)



- ① LI-16 (*Jugu*)
- ② TB-14 (*Jianliao*)
- ③ N-UE-14 (*Naoshang*)
- ④ LI-14 (*Binao*)
- ⑤ SI-10 (*Naoshu*)
- ⑥ SI-9 (*Jianzhen*)
- ⑦ N-UE-12 (*Yingshang*)

Study Questionnaire

Please place a mark along the line which most closely approximates the amount of shoulder pain you are experiencing.

[-----]
None Severe

Please answer Yes or No to the following questions to assess your ability to perform the following tasks without difficulty.

Are you able to comb your hair?	Y	N
Are you able to put on your shirt?	Y	N
Are you able to reach the cupboard above your head?	Y	N
Are you able to brush your teeth?	Y	N
Are you able to fasten a garment behind your back?	Y	N