Johansson K, Bergstrom A, Schroder K, Foldevi M. Subacromial corticosteroid injection or acupuncture with home exercises when treating patients with subacromial impingement in primary care—a randomized clinical trial. Family Practice 2011; 28:355–365.

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Design: Randomized controlled trial

Objective: To determine which treatment, subacromial injection of corticosteroids or a series of 10 manual acupunctures combined with home exercises, is significantly superior in decreasing pain and improving shoulder function for patients with subacromial impingement syndrome (SIS).

Population /sample size/setting:

- 117 consenting patients with shoulder pain located in the deltoid area provoked by elevation of the arm were recruited from one of five primary health care centers in Sweden during 2004-07. Initially 117 enrollees received the allocation intervention and met study criteria, but 13 were lost to follow-up, and 13 others were non-compliant; discontinued treatment (2), changed treatment group (8) or were referred to surgery (3), leaving 91 patients for the final analyses. Of the 91 patients, 53 were females, 38 were males, and mean age was 50.5.
- Eligibility criteria included the diagnosis of SIS, ages 30 to 65, pain located in the proximal lateral aspect of the upper arm for at least 2 months, and a positive Neer impingement test. In addition, at least 3 of the following were positive: Hawkins-Kennedy impingement sign, Jobe supraspinatus sign, Neer impingement sign, and painful arc between 60 and 120^0 during active abduction.
- Exclusion criteria included malignancy, osteoarthritis of the glenohumeral joint, skeletal abnormalities, polyarthritis, rheumatoid arthritis, fibromyalgia, previous fractures, surgery, dislocations, instability, suspicion of frozen shoulder, cervical spine issues, having received acupuncture or similar exercises, a corticosteroid injection in the last 2 months, ruptured rotator cuff, bursitis, or communication problems.
- For allocation of the participants, a computer-generated list of random numbers was used by the study coordinator, who was not involved in the treatments or assessments.
- All clinicians (three GPs and three PTs) involved in treatment were blinded to the assessments performed by the research PTs during the study and vice versa.

Interventions:

- All participants were randomized to one of two treatment protocols either the corticosteroid group or the acupuncture group.
- The corticosteroid group (n=49) received an injection of 1 ml of Depomedrone (40 mg methylprednisolone) and 8 to 10 ml of 1% prilocaine. Patients were also informed that if the first injection had a doubtful effect, they could get a second injection.
- The acupuncture group (n=42) started manual acupuncture in addition to a home exercise program within 1 week of inclusion. The treating PT used standardized needle placement in defined acupuncture points. Acupuncture was repeated twice weekly for 5 weeks, and each treatment session lasted 30 minutes. After insertion into the defined points, the

needle was rotated or stimulated a few seconds until ‘deqi’ was experienced by the patient. Three stimulations were performed immediately after needle insertion and again after 15 and 30 minutes. The home exercise program involved two parts. The first part was targeted towards maintaining or restoring motion and to stimulate circulation in the rotator cuff using many low-intensity repetitions without provoking pain from the tissues involved. The second part was targeted towards strengthening the rotator cuff with the arm in a neutral position to avoid impingement.

Main outcome measures:

- Primary outcomes were pain and shoulder function and secondary outcomes were health-related quality of life (HRQL) and the patients’ global assessment of change. The assessments were performed at baseline and then repeated after 6 weeks and 3, 6 and 12 months after the date of the initial visit.
- The research physical therapists who performed all examinations and assessments, were blinded to the treatment group assignments throughout the study.
- Pain and shoulder function were assessed with the Adolfsson–Lysholm shoulder assessment score (AL-score). It has a maximum score of 100 points for no pain and no shoulder disability initially developed for patients with SIS. Its intra-observer reliability was found to be stable over time for patients with subacromial pain.
- The EuroQol-five dimension self-report questionnaire (EQ-5D) was used to evaluate HRQL. This instrument has two parts: 1) the EQ-5D descriptive system resulting in a health state between –1.0 (worst health) and 1.0 (full health). 2) The EuroQol Visual Analogue Scale (EQ-VAS) is a 20-cm vertical line from 0, ‘worst imaginable health state’, to 100, the ‘best imaginable health state’, and the patients mark their current state. Both parts were reported to be valid and reliable for self-assessed HRQL. At each follow-up, the patients’ global assessment of change in symptoms because of the treatment was registered on a 5 point scale with fixed alternatives: worse, unchanged, small improvement, large improvement or recovered.
- One-fourth of the patients in the corticosteroid group (12 of 49) had a second injection.
- There were no significant differences in the baseline demographic data or outcome measures between the two groups.
- There were no significant differences between the 2 groups in the primary outcome, pain and shoulder function measured by AL-score after 6 weeks and 3, 6 and 12 months.
- Both treatment groups reported a significant improvement over time regarding pain and shoulder function. Both groups had a similar pattern in treatment response.
- There were no significant differences between the 2 groups in the secondary outcome, HRQL (health-related quality of life) after 6 weeks and 3, 6 and 12 months.
- HRQL improved significantly within the respective treatment groups compared with baseline, both for the EQ-5D descriptive system and for the EQ-VAS.
- The global impression of change was in favor of the acupuncture group at the 6-month assessment. Thirty of 42 (71%) patients rated large improvements or reported that they were recovered in the acupuncture group compared with 23 of 47 (49%) patients in the corticosteroid group. At the 12-month assessment, there was no difference between the 2 groups.
- The only adverse events reported were minor complications associated with needle penetration during acupuncture.

Authors' conclusions:

- Neither treatment was superior in decreasing pain and improving shoulder function.
- Both treatments showed a significant positive change in pain and shoulder function and in HRQL compared with baseline during a 12-month follow-up.
- The long-term results are probably a combination of a positive treatment effect and the natural course of the disease.
- Both the corticosteroid injection and acupuncture have an analgesic effect, which probably explains part of the significant improvement in both groups from baseline, especially over the short-term. Pain highly influences most patients' ability to perform shoulder activities in everyday life, and decreased pain probably enhances the function of the shoulder muscles as well.
- Both treatments can be recommended for patients with SIS seeking primary care, and the choice could be influenced by the accessibility of the treatment and the individual patient's preference.
- There is a need for future clinical research emphasizing the dose-response relationship of different exercises for patients with SIS.

Comments:

- General baseline characteristics and outcome measures were evaluated for the 2 groups, and there were not any underlying significant differences between the 2 groups.
- All clinicians involved in treatment of patients were blinded to the assessments performed by the research physical therapists (PTs) during the study and the research PTs were also blinded to the patients' treatment groups.
- This was a homogeneous study that excluded selection bias that could have impacted results by including only patients with SIS and using very precise inclusion criteria that excluded other shoulder pathologies without using MRI or diagnostic ultrasound.
- This study followed the Consort 2010 guidelines and is a high level RCT.
- Inclusion of a third placebo group would have made it possible to determine the size of the specific treatment effect.
- One limitation of the study is that both acupuncture and home exercise, both known to be valid treatments, were included in the same treatment group. It is impossible to differentiate if the acupuncture, home exercise, or both contributed to the positive effects exhibited by this treatment group.
- One limitation with the standard home exercise program utilized in this study was that it lacked individual progression, for example, of increased resistance for excessive muscle strength. A higher intensity and additional eccentric exercises might have been more effective than the standard exercise program used.
- The patients that dropped out of the study were similarly distributed in both treatment groups and had similar baseline characteristics, and their inclusion in the analysis would probably not have had a major influence on the comparisons.
- The patient's expectations and treatment preference can influence the self-assessed outcomes used in this study. This can be a type of information bias. Unfortunately, no preference data was collected and was not adjusted for during the randomization procedure.

- The acupuncture group had 10 visits whereas the corticosteroid group had only one, and it is possible that more visits could be a positive factor that played into a placebo effect.

Assessment*:*

- This study is adequate for some evidence that both subacromial corticosteroid injection and a series of 10 acupuncture treatments combined with home exercises significantly decreased pain and improved shoulder function in patients with SIS, but neither treatment was significantly superior to the other.