

Dogru H, Basaran S, and Sarpel T. Effectiveness of therapeutic ultrasound in adhesive capsulitis. Joint Bone Spine 2008; 75:445-450.

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Design: Randomized clinical trial

Objective: To compare the effectiveness of therapeutic ultrasound aimed at restoring range of motion (ROM) and function and reducing pain of the shoulder with a placebo sham ultrasound group for the treatment of adhesive capsulitis.

Population /sample size/setting:

- 49 volunteer patients (mean age = 55, 21 males, 28 females) with a diagnosis of idiopathic adhesive capsulitis were recruited from an outpatient clinic of Cukurova University in Turkey.
- Eligibility criteria included shoulder pain of minimum 3 months duration with no major trauma, $\geq 25\%$ loss of shoulder motion in all planes, pain with motion with a minimum visual analogue scale (VAS) score of 40 mm, and normal findings on radiographs of the glenohumeral joint.
- Exclusion criteria included secondary adhesive capsulitis due to rotator cuff tears, fractures, dislocations, arthritis, malignancy, reflex sympathetic dystrophy, and medical conditions such as cardiac diseases, infections and coagulation disorders.
- All participants answered questions about their demographics and medical history, underwent a routine systemic exam and a neurologic exam, and were measured for both active and passive ROM. Serum samples were obtained and shoulder X-rays were taken.

Interventions:

- All patients were assessed by the same physician who was blind to the treatment groups. Fifty patients were numbered sequentially and assigned to either the ultrasound (US) (n=25) group or placebo (sham US) (n=24) group by another physician. One patient from the sham US group dropped out during the first week.
- The ultrasound group received real ultrasound and the sham US group received imitative ultrasound applied in the same manner only with the ultrasound machine turned off.
- Participants in both groups received a physical therapy program every day for 2 weeks except weekends (10 sessions). Physical therapy sessions consisted of superficial heat for 20 minutes using hot packs, ultrasound or sham ultrasound application for 10 minutes, followed by an exercise program for 20 minutes. The exercise program was the same for both groups and consisted of Codman's exercises (passive pendulum) and wall climbing followed by glenohumeral joint stretching exercises to the patient's tolerance.
- After the physical therapy program, a home exercise program consisting of Codman exercises, active ROM and stretching exercises was advised for both groups. Compliance with the home exercise program was recorded daily for 3 months on a chart which was given to the patients at the end of the physical therapy treatment sessions.

Main outcome measures:

- The primary outcome variable used to measure pain and disability was the total Shoulder Pain and Disability Index (SPADI) score. Measurements were taken at baseline, after the 10th physical therapy session (post-treatment), and at 3 months.
- Secondary outcome measures included 4 shoulder ROM measurements (abduction, flexion, internal rotation, and external rotation), and pain with motion using the visual analog scale (VAS) pain score. Assessments were given at baseline before treatment, after the 10th physical therapy session (post-treatment), and at 3 months. The Short Form-36 (SF-36) was also used to assess general health status and was administered at baseline and again at 3 months.
- There was no statistically significant difference between groups with respect to age and gender or other demographic variables.
- For the SPADI outcome variables, improvements over time in total SPADI scores, and in SPADI pain and SPADI disability subscales were significant within each group. For the SPADI outcome variables, only the baseline SPADI subscale score of pain was significantly different between the groups (66.9 US vs 57.7 sham US). No other significant differences between the groups were detected for any other SPADI scores.
- Baseline ROM measurements did differ between the 2 intervention groups. Statistically significant differences for the baseline pretreatment values of passive abduction, flexion, internal and external rotation were detected between groups and these ROM values were worse in the US group. Therefore all results were reported as improvements in shoulder ROM and then these differences were compared between groups.
- Statistically significant improvements were detected within both groups for all 4 measures of ROM. Significantly higher improvements were observed in the US group vs. the sham US group from baseline to post-treatment for flexion (29.4⁰ vs 21.7⁰) and internal (22.9⁰ vs 11.0⁰) and external rotation (23.2⁰ vs 15.4⁰), and again from baseline to 3 months for internal (27.6⁰ vs 12.8⁰) and external rotation (30.7⁰ vs 19.4⁰).
- For shoulder pain with motion (VAS), statistically significant improvements were detected within each group over the 3 time measurements, but no statistically significant differences between groups were seen for these 3 measurements over time.
- There was no statistically significant difference in the total SF-36 or in the physical component summary subscale (PCS) or mental component summary subscale (MCS) between the two groups at baseline or at 3 months.
- Home exercise compliance of the sham US group was significantly higher than the US group (76.6 days vs. 67.1 days).

Authors' conclusions:

- Results suggest that ultrasound compared with sham ultrasound give no relevant benefit in the treatment of adhesive capsulitis.
- Home exercise compliance of the sham US group was higher than the US group, and this may have contributed to the improvement of outcome measures in the sham US group.
- The major limitation of the study may be due to the relatively small number of patients in each group.
- Randomized placebo-controlled trials of larger populations are needed to clarify the effectiveness of ultrasound in adhesive capsulitis.

Comments:

- The participants did not know if they were receiving real ultrasound or sham ultrasound. The physical therapists conducting the therapy and exercise sessions could have been blinded to the participants' intervention groups, but it is not clear if they were.
- It is not known how many physical therapists conducted the therapy sessions and if they treated equal numbers of US group and sham US group participants and if their therapy sessions and instructions for exercise were administered the same way.
- Minimum sample size calculations required a minimum of 29 subjects in each intervention group. This study included only 25 and 24 in each group. The relatively small number of patients in each group resulted in an underpowered study which may not have been sensitive enough to detect a difference in SPADI scores between intervention groups. The small sample size would result in great uncertainty in the estimate of the effect.
- Limiting the study protocol to 2 weeks of treatment may have impacted the ability of the study to achieve the maximal therapeutic benefit of ultrasound for many patients and thereby reduced the ability of the study to show an effect of the ultrasound. This would underestimate the effect of the intervention.
- Home exercise compliance of the sham US group (77 days) was higher than the US group (67 days), and this could have contributed to the improvement of outcome measures in the sham US group resulting in an underestimation of the effect. However, over the course of 90 days of home exercise, this 11% difference in subjective compliance is really not clinically important and the authors may have overestimated this difference.
- All 4 baseline ROM measurements were statistically lower in the US group than in the sham US group. Improvements in ROM from baseline to 3 months were all larger in the US group than in the sham US group, but the differences were only statistically significant for internal and external rotation. The small differences observed in ROM measurements between groups may not be clinically important. The US group may have demonstrated larger improvements in ROM because they started with lower baseline ROM measurements, and had more room for improvement. The actual ROM measurements at 3 months for both groups are very similar, suggesting a ceiling effect where both groups reached their maximum ROM. Only external rotation at 3 months is significantly different between groups. The non-comparability of the baseline ROM measurements between groups clouds the overall improvements in ROM.
- Significant improvements were observed over time in all ROM measurements, and in all SPADI and VAS scores for both groups. It is possible that these measured therapeutic benefits came from the other components of the rehabilitation program and not from the ultrasound or sham ultrasound interventions.

Assessment:

- This study is adequate for some evidence that ultrasound compared with sham ultrasound as part of an overall rehabilitation protocol including exercise, stretching, and heat treatments have approximately equal effects in the treatment of patients with adhesive capsulitis.