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Original article

Effectiveness of therapeutic ultrasound in adhesive capsulitis☆

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Abstract

Objective: There is a lack of evidence about the effectiveness of therapeutic ultrasound (US) compared with placebo US in the treatment of adhesive capsulitis. This study was performed to assess the effectiveness of therapeutic US in the treatment of adhesive capsulitis.
Methods: Forty-nine patients with adhesive capsulitis were randomized to US ($n = 25$) and sham US ($n = 24$) groups. Superficial heat and an exercise program were given to both groups. Ultrasound was applied to US group and imitative ultrasound was applied to sham US group for 2 weeks. Shoulder range of motion (ROM), pain and Shoulder Pain and Disability Index (SPADI) were assessed at the beginning, after treatment and after 3 months (control). Short Form-36 (SF-36) was applied for assessing general health status at the beginning and after 3 months. Compliance with the home exercise program was recorded daily on a chart for 3 months.
Results: Shoulder ROM, pain with motion, two subscales and total score of SPADI and physical component summary score of SF-36 were improved significantly in both groups after the treatment and after 3 months ($p < 0.0001$). Improvements in flexion, inner and outer rotation values were significantly higher in the US group when we compared the differences between post- and pre-treatment values of shoulder ROM. The differences between control and pre-treatment values of inner and outer rotation were also significantly higher in the US group ($p = 0.002$ and $p = 0.02$ respectively). No significant difference was detected in pain, SPADI and SF-36 scores between groups. The exercise compliance was significantly higher in the sham US group ($p = 0.04$).
Conclusion: Our results suggest that US compared with sham US gives no relevant benefit in the treatment of adhesive capsulitis. Effectiveness of US might be masked by worse pre-treatment values of the US group and higher exercise compliance of the sham US group.

Keywords: Adhesive capsulitis; Ultrasound; Sham ultrasound; SPADI; SF-36

1. Introduction

Adhesive capsulitis is a disabling and painful condition characterized by active and passive limitation of the shoulder range of motion (ROM). Shoulder motion and daily activities are restricted gradually, causing disability [1–4]. Primary adhesive capsulitis is characterized by idiopathic fibrosis of the joint capsule. Secondary adhesive capsulitis occurs following some predisposing factors or seen together with some diseases. Female gender, age over 40 years, rotator cuff lesions, diabetes mellitus, thyroid diseases, stroke, lung diseases, myocardial infarction, cervical spine disorders and reflex sympathetic dystrophy syndrome are the factors associated with adhesive capsulitis [1,5]. Adhesive capsulitis is more common in females and the peak age is 56 years. The natural course of the disease is divided into three phases which may not be clearly separated from each other: painful freezing phase (10–36 weeks), adhesive phase (4–12 months) and resolution phase (12–42 months). Laboratory tests are normal and the diagnosis is mainly clinical [2].

The aim of the treatment in adhesive capsulitis is to relieve pain, and improve range of motion and disability. Patient advice, nonsteroidal anti-inflammatory drugs, intra-articular injections, physical therapy modalities and exercise can be listed among the conventional treatment modalities. Arthrographic distension, manipulation under anesthesia, arthroscopic release and open surgery are the other treatment options [1–3,5–7].

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Physical therapy is among the first-line therapeutic choices in adhesive capsulitis. Conventionally used physical therapy regimens in adhesive capsulitis are heat modalities, analgesic modalities (transcutaneous electrical nerve stimulation (TENS)) and exercise [3,5,8]. Codman's exercises are those most frequently used to improve the range of motion. The emphasis in therapy is on passive stretching of the shoulder capsular contracture in all planes of motion [9]. The literature on physical therapy in treating adhesive capsulitis is controversial and its efficacy has not been established [3,5]. In a recently published review, it has been reported that physical therapy alone had little benefit in treating adhesive capsulitis. Although steroid injection was effective, the best approach was combination with physical therapy [2].

Ultrasound (US), which is a deep heat modality, has been used for more than 60 years in clinics but the effects of US in pain, soft tissue lesions and musculoskeletal injuries remains questionable. US is effective in increasing the ROM of periarthritic shoulders. Collagen and tendon extensibility increases as temperature increases. As a result, stretching should begin during heating and continue as the tissue cools and sets [10]. US was found to be more effective than placebo US in calcific tendonitis in a review about the effectiveness of therapeutic US, whereas in another review it was found to be ineffective in soft tissue disorders of the shoulder [11,12]. A recent evidence-based guideline panel came to the conclusion that although therapeutic US was effective in the treatment of calcific tendonitis of the shoulder, there was no evidence that it was beneficial for other forms of shoulder pain (e.g. capsulitis, bursitis, tendonitis) [13].

Studies in the literature investigating the effects of US in the treatment of adhesive capsulitis compare US with different physical treatment modalities or intra-articular injections. However, clear evidence of effectiveness of US in the treatment of adhesive capsulitis compared with placebo US is lacking. In this study our aim was to investigate the efficacy of US using placebo US in patients with adhesive capsulitis.

2. Methods

This study was conducted at the outpatient clinic of the Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Cukurova University. The local ethics committee approved the study protocol and written informed consent was taken from all patients enrolled in the study.

2.1. Subjects

The study population consisted of 49 patients between 41 and 72 years of age. The criteria for inclusion in the study were (1) shoulder pain of minimum 3 months duration with no major trauma, (2) $\geq$25% loss of shoulder motion in all planes, (3) pain with motion with a minimum visual analogue scale (VAS) score of 40 mm, (4) normal findings on radiographs of the glenohumeral joint and (5) absence of arthritis, malignancy, and medical conditions such as cardiac diseases, infections and coagulation disorders. Patients with secondary adhesive capsulitis due to rotator cuff tears, fractures, dislocations and reflex sympathetic dystrophy were excluded from the study group.

The patients were questioned about their demographic characteristics and medical history. Routine systemic examination as well as neurologic examination and measurement of both active and passive range of motion (ROM) were made. Documenting the initial ROM, especially of passive motion, is critical in determining the efficacy of treatment plan in adhesive capsulitis [14]. Therefore, passive shoulder ROM of the patients was measured in all planes with a long-arm goniometer while the patients were lying supine [15].

Serum samples were obtained to evaluate complete blood count, erythrocyte sedimentation rate and routine biochemical analysis for exclusion of secondary factors. Shoulder X-rays were taken, and evaluated by the same physician.

Sixty-seven patients with a diagnosis of idiopathic adhesive capsulitis were evaluated between August 2005 and January 2006. Fourteen of these patients did not meet the inclusion criteria and three refused to participate because of transport problems. All patients were assessed by the same physician who was blind to the treatment groups (first author). Fifty patients were numbered sequentially and assigned to either the ultrasound (US) group or placebo (sham US) group by another physician (second author). One patient from the sham US group discontinued the intervention at the beginning of the first week due to personnel reasons. Twenty-five patients in the US group and 24 patients in the sham US group were assessed for final evaluation.

2.2. Study protocol

Following pre-treatment evaluation of shoulder ROM and pain with motion (VAS), Shoulder Pain and Disability Index (SPADI) and Short Form-36 (SF-36) were assessed on the patients. Shoulder ROM, pain and SPADI were reassessed after the 10th session of the treatment (post-treatment) and at the 3rd month (control), whereas the SF-36 questionnaire was carried out again on control evaluation.

The SPADI is a disease-specific, self-administered instrument that measures the impact of shoulder pathology in terms of pain and disability. This instrument includes 13 items in two subscales: pain (5 items) and disability (8 items). The SPADI has two versions: original VAS version and 0–10 numeric scaled version. The numeric version is easier to apply and used more frequently. The questions are asked using the preceding week as the frame of reference. Patients mark their response on a 100 mm numeric scaled line where 0 = "no pain" and 100 = "worst pain imaginable" for the 5 pain items and 0 = "no difficulty" and 100 = "so difficult, it required help" for the 8 disability items. The SPADI is scored 0–100 by averaging the scores from the two subscales [16–18].

SF-36 is a generic, self-administered instrument used to assess general health status in 8 domains. The results can be assessed as two summary subscales; physical component summary subscale (PCS) and mental component summary subscale (MCS). PCS is composed of physical function, physical role,

bodily pain and general health subscales. MCS is composed of vitality, social function, emotional role and mental health subscales. The scores range between 0 and 100 and lower scores represent worse health status [19].

2.3. Intervention

Superficial heat (hot pack, HP) and exercise program were given to both groups, whereas ultrasound was applied to the US group and imitative ultrasound was applied to the sham US group. The patients received a physical therapy program every day for 2 weeks except weekends. 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 during 3 months on a chart which were given to the patients at the end of the treatment. Patients were called by phone every 2 weeks and reminded to perform the exercises and record the chart daily. The percentage of exercise compliance was calculated from these charts on the control evaluation.

Physical therapy sessions consisted of superficial heat for 20 min, ultrasound application for 10 min followed by exercise program for 20 min. Superficial heat was administered by use of hot packs (60 °C) for 20 min. The US group received continuous US with 3 MHz frequency and 1.5 W/cm^2 intensity (Intelect® Mobile Ultrasound device, Chattanooga Group) with a transducer head of 5 cm^2 for 10 min. After coating the skin with an aquasonic gel, US was delivered by moving the applicator over the anterior, superior and posterior regions of the target joint in slow, overlapping strokes. In the sham US group the skin was also covered with an aquasonic gel and then ultrasound was applied in the same manner except the device was not switched to ''on''. The exercise program consisted of Codman's exercises and wall climbing followed by glenohumeral joint stretching exercises to the patient's tolerance.

The subjects were permitted only to take simple analgesics (paracetamol, maximum 1000 mg/day) for pain, but this use was not quantified.

2.4. Statistical analysis

The total SPADI score was used as the primary outcome measure for this trial. Sample size was calculated with an expected parameter estimate based on a pilot study performed in our department. Assuming a mean of 64.5 total SPADI in the US group and a mean of 53.8 in the sham US group with a 14.0 standard deviation, the minimum sample size thus required was to be approximately 29 in each study group within a 95% confidence and 80% power limit. Adding 15% for lost to follow-up, 67 patients were included in the study. Statistical analyses were performed using the statistical package SPSS version 12.0 for Windows. The Mann–Whitney *U*-test was used for comparing the variables between the two groups. The Wilcoxon test was used to evaluate pre- and post-treatment values within groups. Repeated measurements more than twice were analyzed by Friedman test within groups. The level of statistical significance was set at $p < 0.05$.

3. Results

Forty nine patients with a mean age of 55.3 ± 7.6 years were enrolled in the study. Demographic features of the patients are given in Table 1. There was no statistically significant difference between groups with respect to age and gender. Although duration of disease was longer in the US group, the difference was not significant. Eighteen of the patients (36.7%) had diabetes mellitus. The characteristics of the patients with diabetes mellitus were similar to the other patients.

Shoulder ROM was examined before treatment, after the 10th session (post-treatment) and at the 3rd month of the treatment (control). Statistically significant differences for the pre-treatment values of passive abduction, flexion, inner and outer rotation were detected between groups ($p = 0.03$, $p = 0.01$, $p = 0.001$, and $p = 0.000$ respectively) and these values were worse in the US group (Table 2). Therefore we decided to give the results as improvement in shoulder ROM (difference between post–pre-treatment and control–pre-treatment values) and compare these differences between groups. Post–pre-treatment and control–pre-treatment values are shown in Table 2. Improvements of post–pre-treatment values of shoulder flexion, inner and outer rotation were significantly higher in the US group ($p = 0.04$, $p = 0.002$ and $p = 0.02$, respectively). Control–pre-treatment improvements of inner and outer rotation values were also significantly higher in the US group ($p = 0.001$ and $p = 0.02$, respectively). After analyzing the repeated measurements of abduction, flexion, and inner and outer rotation, statistically significant improvements were detected within both groups ($p < 0.0001$).

Shoulder pain with motion (VAS) was assessed before the treatment, after the 10th session and at the 3rd month of treatment. Statistically significant improvements were detected within both groups ($p < 0.0001$) for the analysis of repeated measurements of pain (Table 3). There was no statistically significant difference between groups for these measurements ($p = 0.59$, $p = 0.56$, $p = 0.83$).

Shoulder pain and disability was assessed using SPADI before the treatment, after the 10th session and at the 3rd month of the treatment. Only the pre-treatment score of pain subscale was significantly different between the groups ($p = 0.04$). No significant differences were detected for the post-treatment and control values between the groups. Improvements in

Table 1
Demographic features of the patients suffering from adhesive capsulitis

	US ($n = 25$)	Sham US ($n = 24$)	Total ($n = 49$)
Age (years)	53.9 ± 7.8 (41–72)	56.8 ± 7.3 (46–70)	55.4 ± 7.6 (41–72)
Gender (M/F)	11/14	10/14	21/28
Duration of disease (months)	6.3 ± 3.5 (3–12)	5.2 ± 2.9 (3–12)	5.7 ± 3.3 (3–12)
Right/left shoulder	7/18	15/9	22/27
Diabetes mellitus	8/25	10/24	18/49

Table 2
Shoulder range of motion (ROM) values and improvements in ROM values of the patients between post–pre-treatment and control–pre-treatment values in ultrasound (US) and Sham US groups

	US	Sham US	p
Abduction			
Pre-treatment	101.4 ± 20.9	113.5 ± 14.1	0.03
Post-treatment	142.8 ± 25.9	146.0 ± 26.2	0.72
Control (3rd month)	147.8 ± 30.1*	148.0 ± 26.5*	0.98
Post–pre-treatment	41.5 ± 15.2	32.5 ± 18.5	0.06
Control–pre-treatment	45.4 ± 26.9	34.4 ± 21.3	0.15
Flexion			
Pre-treatment	133.2 ± 16.0	143.7 ± 16.3	0.01
Post-treatment	162.6 ± 12.4	165.4 ± 15.0	0.31
Control (3rd month)	163.7 ± 16.5*	168.5 ± 13.0*	0.34
Post–pre-treatment	29.4 ± 15.2	21.7 ± 11.4	0.04
Control–pre-treatment	30.8 ± 19.6	24.6 ± 12.9	0.21
Inner rotation			
Pre-treatment	29.2 ± 15.7	47.3 ± 18.8	0.001
Post-treatment	52.2 ± 15.7	58.3 ± 15.5	0.12
Control (3rd month)	57.4 ± 13.8*	60.9 ± 15.3*	0.21
Post–pre-treatment	22.9 ± 13.4	11.0 ± 11.9	0.002
Control–pre-treatment	27.6 ± 17,5	12.8 ± 13.4	0.001
Outer rotation			
Pre-treatment	34.8 ± 14.7	55.8 ± 17.2	0.000
Post-treatment	58.0 ± 16.6	71.3 ± 14.9	0.004
Control (3rd month)	65.7 ± 19.4*	75.4 ± 15.5*	0.05
Post–pre-treatment	23.2 ± 12.4	15.4 ± 12.4	0.02
Control–pre-treatment	30.7 ± 17.3	19.4 ± 14.2	0.02

*Significant improvement in repeated measures of abduction, flexion, inner and outer rotation ($p < 0.0001$).

Table 3
Pain with motion (VAS), SPADI scores and SF-36 summary scores of the patients in the US and sham US groups

	US ($n = 25$)	Sham US ($n = 24$)	p
Pain with motion (VAS)			
Pre-treatment	80.8 ± 18.2	78.0 ± 18.4	0.59
Post-treatment	39.6 ± 25.3	40.7 ± 20.3	0.56
Control (3rd month)	24.8 ± 29.9*	23.6 ± 25.5*	0.83
SPADI pain			
Pre-treatment	66.9 ± 13.8	57.7 ± 18.0	0.04
Post-treatment	40.1 ± 18.6	35.6 ± 13.7	0.37
Control (3rd month)	31.0 ± 20.0*	25.2 ± 18.3*	0.39
SPADI disability			
Pre-treatment	66.6 ± 14.6	62.1 ± 17.3	0.43
Post-treatment	37.0 ± 18.6	38.2 ± 17.8	0.72
Control (3rd month)	29.5 ± 21.6*	26.4 ± 19.6*	0.50
SPADI total			
Pre-treatment	66.5 ± 13.7	63.1 ± 13.8	0.39
Post-treatment	38.6 ± 17.4	38.1 ± 15.9	1.00
Control (3rd month)	30.0 ± 20.9*	25.5 ± 17.8*	0.45
SF-36 PCS			
Pre-treatment	38.9 ± 7.9	36.6 ± 9.8	0.36
Control (3rd month)	44.2 ± 8.4*	44.6 ± 8.8*	0.83
SF-36 MCS			
Pre-treatment	43.5 ± 10.2	42.0 ± 7.7	0.62
Control (3rd month)	44.8 ± 11.5	43.8 ± 10.6	0.81

*Significant improvement in repeated measures of pain with motion (VAS), SPADI pain, disability and total scores and PCS score of SF-36 ($p < 0.0001$).

pain and disability subscales and total SPADI scores were significant in both groups (Table 3). Comparison of SPADI total score between US and sham US groups are shown in Fig. 1.

General health status of the patients was evaluated using SF-36 before treatment and at the 3rd month. There was no statistically significant difference in the 8 domains of SF-36 and PCS and MCS summary scales between the two groups. Physical role, bodily pain and PCS scores improved significantly in the US group, whereas bodily pain, vitality and PCS scores improved significantly in the sham US group. PCS and MCS scores of the patients are given in Table 3.

The percentage of exercise compliance was calculated from the charts given to the patients on the control evaluation. Exercise compliance of the sham US group was significantly higher than the US group (76.6 ± 15.2 vs. 67.1 ± 14.9 respectively, $p = 0.04$).

4. Discussion

Heat agents (superficial and deep), analgesic modalities and exercise are among the conventionally used physical therapy regimens in adhesive capsulitis [8]. Although the literature is controversial about its effectiveness, physical therapy is among the first-line therapeutic choices in adhesive capsulitis [3,5,7,20].

Exercise and two different deep heat modalities (short wave diathermy and ultrasound) were applied to the patients with adhesive capsulitis by Mao et al. [6], who found that deep heat modalities improve ROM and joint space capacity especially in early cases. The lack of a control group makes it difficult to state that physical therapy interventions caused this clinical and radiographic improvement. In our study we

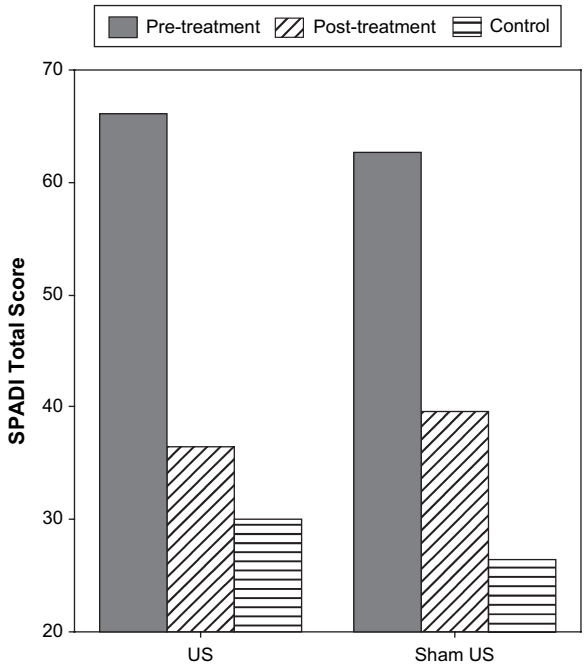

Fig. 1. Comparison of Shoulder Pain and Disability Index (SPADI) score between US and sham US groups.

investigated the efficacy of US compared with placebo US in patients with adhesive capsulitis and found significant improvements in ROM, pain, SPADI scores and PCS score of SF-36 in both groups.

Carette et al. [21] compared the efficacy of intra-articular corticosteroid injection, supervised physiotherapy program (consisting of TENS, mobilization techniques and active ROM exercises), combination of the two and placebo in the treatment of adhesive capsulitis. Subjects were also given a simple home exercise program which they followed for 1 year. ROM improved in all groups at the end of therapy (4 weeks). The combined group had significantly greater improvement in ROM than other groups. The total SPADI scores improved more in combination and corticosteroid groups. No significant difference was detected in the physiotherapy group compared with the placebo group. However, in this study the placebo group received saline injection whereas imitative (sham) US was applied in our study. The treatment groups were similar to the placebo group with respect to all outcome measures by the end of 12 months.

Effectiveness of US was assessed together with other physical therapy interventions (hot pack, interferential current and exercise) in the management of shoulder disorders such as supraspinatus tendinosis, supraspinatus partial rupture, rotator cuff rupture and bicipital tendinosis. ROM (except outer rotation in the sham US group), SPADI and Health Assessment Questionnaire (HAQ) scores were improved significantly in both groups after 3 weeks. No significant differences were detected between groups [4]. However, adhesive capsulitis was not investigated and only early response to physical therapy was presented in this study.

The Cyriax method, which is a combination of deep friction massage and manipulation, was compared with physical therapy consisting of superficial heat (HP), deep heat (short wave diathermy, SWD) and exercise in a study conducted by Uysal and Kozanoglu [5]. The results of the Cyriax group, in terms of shoulder ROM and pain, were better than SWD in their study.

Pajareya et al. [3] investigated the effects of a physical therapy program consisting of SWD mobilization and stretching exercises in patients with adhesive capsulitis. Ibuprofen and general advice were given to both study group and placebo group. SPADI scores, abduction and inner rotation improved significantly in the study group. SWD, which is a deep heat modality like US, was found to be effective for a short time period in this study and was supported by the early use of physical therapy in adhesive capsulitis.

A single intra-articular corticosteroid injection followed by home exercise was compared with a physical therapy program (consisting of hot pack, US and exercise) by Arslan and Celiker [22]. Improvement in ROM and VAS scores were similar in both groups at the end of 12 weeks. These results are controversial, suggesting the evidence that intra-articular corticosteroid injection is superior to physical therapy.

Exercise interventions in adhesive capsulitis are shown to have beneficial effects [23–26]. Callinan et al. [23] performed hydroplasty combined with therapeutic exercise in 60 patients with adhesive capsulitis and determined significant improvements in ROM values. The effects of specific shoulder stretching exercises were investigated and significant improvements were detected in ROM values and pain [24]. Diercks and Stevens [25] compared supportive therapy and exercises with physical therapy consisting of passive stretching and manual mobilization. At the end of 12 months better outcome was found in the exercise group. Treatment consisting of education regarding frozen shoulder and home stretching instructions (home program) improved shoulder function and health status [26]. In our study 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.

Our results suggest that US compared with sham US give no relevant benefit in the treatment of adhesive capsulitis. The limitation of our study may be the relatively small number of patients in each group. Randomized placebo-controlled trials of larger populations are needed to clarify the effectiveness of US in adhesive capsulitis.

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