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Efficacy of therapeutic ultrasound in treatment of adhesive capsulitis: A prospective double blind placebo-controlled randomized trial

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Abstract.
BACKGROUND: In treatment of adhesive capsulitis, deep heating agents have been shown to have positive effects on pain and function.
OBJECTIVE: To evaluate if addition of ultrasound used in treatment of adhesive capsulitis will provide additional benefits.
METHODS: Thirty patients with adhesive capsulitis were included in a prospective, double-blind, randomized controlled trial. Hotpack, TENS (Transcutaneus Electrical Nerve Stimulation), exercise and active ultrasound therapies were applied to the first group ($n = 15$), whereas sham ultrasound was applied to the second group ($n = 15$) in addition to hotpack, TENS and exercise. The patients were evaluated using joint range of motion, UCLA shoulder scale and Shoulder Disability Questionnaire scales at baseline and at 6th and 24th weeks post-treatment.
RESULTS: When pain and the clinical and functional parameters were compared in both groups, significant improvement was found compared to baseline ($p < 0.001$). At week 24, no difference was found in terms of pain at rest, but all other parameters were improved compared to week 6. When the groups were compared, no difference was found in any comparison between 6th and 24th week ($p > 0.05$).
CONCLUSION: Adding ultrasound treatment to a combination of physical therapy modalities did not provide any additional benefits for the treatment of adhesive capsulitis.

Keywords: Capsulitis, exercise, therapeutics, shoulder, ultrasonic therapy

1. Introduction

Adhesive capsulitis is a soft tissue disorder characterized with pain, rigidity and progressive loss of active and passive range of motion in the glenohumeral joint [1]. Its prevalence in the general population ranges between 2% and 5% [2]. Frequently, women have this disease with a higher rate compared to men

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and it is generally observed between the ages of 40 and 60 years [3]. If the intrinsic anomaly is not found in the shoulder clinical presentation is defined as primary adhesive capsulitis. Adhesive capsulitis may occur secondarily following systemic diseases including diabetes, prolonged shoulder immobilization (trauma, overuse damage or surgery), cardiac diseases, tyrotoxicosis and Parkinson's disease [3,4].

There are different theories about the development of adhesive capsulitis. Hand et al. [5] reported that fibroblastic proliferation as a response to chronic inflammation was involved in the pathogenesis. Bunker et al. [6] compared shoulders with adhesive capsulitis with normal shoulders and patients who had Dupuytren contracture and showed that growth factor and cytokines were slightly higher in adhesive capsulitis and metallaproteinases were absent in control groups.

Adhesive capsulitis characteristically has a 3-phase clinical course. The initial phase starts with shoulder pain and frequently sleep disorders and limitation in active range of motion in the shoulder joint develops together with this severe shoulder pain which cannot be related with a certain cause. In the second phase, fibrotic and adhesive changes occur in the shoulder capsule which is immobilized because of pain and thus both active and passive joint movements are markedly limited. At the end of a mean period ranging between 1 and 3 years, the 3rd phase (remodeling) which is characterized with a slow improvement in joint movements occur [2,3]. Adhesive capsulitis is a self-limiting condition, if it is not treated, but it leads to disability, because complete healing occurs in a period longer than 2 years [7]. The objective of treatment is to decrease pain and improve range of motion and disability [8]. The treatment methods recommended for adhesive capsulitis include rest/education, analgesia, joint mobilization, thermotherapy, massage, therapeutic exercises and physical therapy, acupuncture, corticosteroid injection, laser therapy, capsular distention, manipulation under anesthesia, nerve blockages and arthroscopic capsular relaxation [9].

In treatment of adhesive capsulitis, deep heating agents have been shown to have positive effects on ROM, pain and function [10–12]. Since an increasing energy occurs due to intervention of the reflected waves on the mutual surfaces of different tissues with application of ultrasound and less vascularized tissues preserve heat to a greater extent, it is thought that it is possible to heat bone, joint, capsule and synovial tissue in a good way and thus ultrasound application may lead to an increase in flexibility in the capsule [13,14]. Therapeutic ultrasound has also effects which are shown *in vitro* including contribution to early resolution of inflammation, increasing fibrinolysis, stimulating macrophage-driven mitogenic factors, increasing fibroblast production, speeding angiogenesis, increasing matrix synthesis and increasing tissue tensile strength with more intensive collagen fibrils [15]. In this study, we aimed to observe the effects of therapeutic ultrasound which we used in conservative treatment of adhesive capsulitis on pain, ROM and function.

2. Materials and method

Patients who had a complaint of shoulder pain for at least 3 months and whose passive ranges of motion were compatible with the risk criteria [16] were included in the prospective, randomized, controlled, double-blind study (abduction $< 100°$, external rotation $< 30°$, internal rotation $< 70°$, elevation $< 140°$). Local ethics committee approved for trial. Randomization realized with Random Number Generator program. Written consent was obtained from the patients. After randomization (done by BK), first evaluation and follow-up of outcome measurements were realized by ACT, blnd treatment was performed by TÖB.

The patients who had shoulder instability, cervical radiculopathy, rheumatic or neurological disease, who were using cardiac pacemaker and who received physical therapy or corticosteroid injection in the last one month directed to shoulder, neck and back were not included in the study. In the patients who had positive shoulder impingement tests, subacromial entrapment injection test was performed by giving 10 ml 1% Lidocain into the subacromial space. The patients whose pain was reduced to a great extent and whose active and passive range of motion improved were excluded from the study.

Thirty patients who were diagnosed with primary adhesive capsulitis and who were in phase 2 were randomly divided into two groups. Active ultrasound was applied to the first group and sham ultrasound was applied to the second group. Patients were positioned so that they could not see the ultrasound device to provide blindless. In addition, TENS (transarticular conventional TENS with 4 electrodes, 20 minutes), hot pack (20 minutes) and exercise therapies were applied to both groups.

Ultrasound was applied to the painful shoulder at a dose of 1.5 Watt/cm^2 with a frequency of 1 MHz for

8 minutes continuously and in a circular way in the first group. In the sham ultrasound group, ultrasound was applied in the same way, but at a dose of 0 Watt/cm^2.

Exercise program was planned to include pendulum exercises, stretching exercises, isometric, resistant isometric and isotonic exercises. Especially pendulum exercises were asked to be performed every 2 hours for 5 minutes throughout the day. Use of paracetamol up to 3 g a day was permitted for pain, but recording of the amount of usage was not asked for.

Therapies applied in clinic were continued three days a week for 6 weeks. All patients were evaluated for three times before treatment, at the 6th week after treatment and at the 24th week after treatment. There were no patients lost or withdrawn in the study

2.1. Evaluation criteria

Pain; pain at rest and pain during movement were evaluated by VAS (visual analogue scale) [17].

Joint range of motion; shoulder active abduction and flexion and arm internal and external rotation (at 90°) values were measured by goniometer in the supine position.

Functional status; functional status was evaluated by UCLA (University of California and Los Angeles) shoulder scale. This scale evaluates pain, function, patient satisfaction, flexion *strength* and flexion point of a total point of 35. Pain and function are scored between 1 and 10 points each, active flexion angle, flexion muscle strength and patient satisfaction are scored between 1 and 5 points each. In total, a score of 34–35 is considered an excellent functional outcome, a score of 29–33 is considered a good functional outcome and a score below 29 is considered a poor functional outcome [18].

Shoulder disability questionnaire (SDQ) was used for disability states arising from shoulder problem. SDQ is a disability questionnaire which contains 16 items describing the common states which increase the symptoms belonging to the shoulder. The evaluation covers the last 24 hours. If the specified activity was performed and pain has occurred, the option "yes" was marked, if the activity was performed and no pain occurred, the option "no" was marked and if the activity was not performed in the last 24 hours, the option "not applicable" was marked. The score is calculated with the following formula: [the number of yes/(the number of yes + the number of no)] × 100. A score of zero indicates maximum well-being and a score of 100 indicates maximum disease state [19].

2.2. Statistical analyses

SPSS (Statistical Package for Social Sciences) for Windows 10.0 program was used for statistical analyses. When evaluating the study data, the variables which showed normal distribution were compared using Student's t test and the variables which did not show a normal distribution were compared using Mann Whitney U test in addition to descriptive statistical methods (mean, standard deviation). In comparison of qualitative data, chi-square test and Fisher Exact chi-square test were used. The results were evaluated in a confidence interval of 95% considering a p value of $<$ 0.05 statistically significant. A repeated measures design with 0 between factors and 1 within factor has 1 groups with 15 subjects each for a total of 15 subjects. Each subject is measured 3 times. This design achieves 100% power to test factor W if a Geisser-Greenhouse Corrected F Test is used with a 5% significance level and the actual effect standard deviation is 0.56 (an effect size of 1.57).

3. Results

The ages of the patients ranged between 41 and 77 years and the mean age was 55.66 ± 8.2 years. 14 (46.7%) of the patients were male and 16 (53.3%) were female. The distribution of the groups by demographic properties is shown in Table 1. There was no statistically significant difference between the groups in terms of mean age, complaint periods, gender, education status, occupation classification, marital status and parts where complaints were observed ($p > 0.05$). The dominant hand was the right hand in 93% of our patients. The distribution of involvement of the dominant and non-dominant side was equal (50%).

When the two groups were compared in terms of clinical and functional parameters before treatment, no statistically significant difference was found ($p >$ 0.05).

When pain and clinical parameters before treatment, at the 6th week after treatment and at the 24th week after treatment were compared in the FT + therapeutical ultrasound group, a significant improvement was found both at the 6th week and at the 24th week compared to the values before treatment (Table 2). In comparison of the 6th week and 24th week, all parameters were found to be improved except for pain at rest. These data were also similar in the FT + sham ultrasound group (Table 3).

Table 1
Demographic data of the groups

		Group 1	Group 2	P
Age (Mean ± SD)		55.33 ± 6.59	56.00 ± 9.81	0.091*
Duration of complaint (week) (Mean ± SD)		22.00 ± 14.81	21.00 ± 10.72	0.135*
Sex	Men	7 (46.07%)	7 (46.7%)	1.000**
	Women	8 (53.3%)	8 (53.3%)	
Education level	Uneducated	2 (13.3%)	5 (33.3%)	0.454**
	Primary school	8 (53.3%)	8 (53.3%)	
	High school	2 (13.3%)	1 (6.7%)	
	University	3 (20.0%)	1 (6.7%)	
Job	Housewife	5 (33.3%)	8 (53.3%)	0.533**
	Officer	1 (6.7%)	–	
	Retired	5 (33.3%)	3 (20.0%)	
	Self-employed	4 (26.7%)	4 (26.7%)	
Marital status	Married	14 (93.3%)	14 (93.3%)	1.000**
	Single	1 (6.7%)	1 (6.7%)	
Affected part	Dominant arm	6 (40.0%)	9 (60.0%)	0.273**
	Nondominant arm	9 (60.0%)	6 (40.0%)	

Group 1. Physical Therapy + Therapeutic ultrasound group; Group 2. Physical Therapy + Sham ultrasound group; *Student t test; **Mann Whitney U test.

Table 2
Comparison of pre-treatment, 6th and 24th week post-treatment findings in physical therapy + therapeutic ultrasound group

	PreTreatment	6th week	24th week	Pretreatment-6th week p	Pretreatment-24th week p	6th week-24th week p
	2.80 ± 2.5	0.60 ± 1.45	0	0.003	0.003	0.109
Activity pain	8.40 ± 2.06	2.80 ± 2.11	1.00 ± 1.00	0.001	0.001	0.003
Abduction (degree)	80.33 ± 9.35	118.00 ± 25.69	145.67 ± 30.23	0.001	0.001	0.001
Flexion (degree)	110.00 ± 14.88	140.80 ± 11.51	154.00 ± 9.86	0.001	0.001	0.001
Internal rotation (degree)	28.00 ± 10.29	45.67 ± 18.89	59.00 ± 14.52	0.001	0.001	0.037
External rotation (degree)	19.33 ± 11.73	41.33 ± 18.[illegible]	62.00 ± 18.00	0.001	0.001	0.001
Mean UCLA score	12.73 ± 1.94	25.53 ± 3.[illegible]	29.93 ± 2.02	0.001	0.001	0.001
Mean SDQ score	82.92 ± 16.45	30.42 ± 22.14	7.97 ± 6.50	0.001	0.001	0.001

UCLA: University of California and Los Angeles shoulder scale; SDQ: Shoulder disability questionnaire.

Table 3
Comparison of pre-treatment, 6th and 24th week post-treatment findings in physical therapy + sham ultrasound group

	PreTreatment	6th week	24th week	Pretreatment-6th week p	Pretreatment-24th week p	6th week-24th week p
Resting pain	3.33 ± 2.61	1.53 ± 3.91	0.06 ± 0.26	0.049	0.003	0.078
Activity pain	6.93 ± 2.15	3.33 ± 4.01	1.20 ± 1.21	***0.010***	***0.001***	***0.021***
Active abduction (degree)	78.00 ± 13.34	129.33 ± 30.76	145.00 ± 25.63	0.001	0.001	0.001
Active flexion (degree)	102.00 ± 12.78	142.33 ± 14.50	154.67 ± 13.56	0.001	0.001	0.001
Active internal rotation (degree)	27.00 ± 10.82	45.67 ± 18.31	55.67 ± 17.91	0.001	0.001	0.017
Active external rotation (degree)	25.00 ± 11.49	52.33 ± 10.63	70.00 ± 12.95	0.001	0.001	0.001
Mean UCLA score	12.33 ± 1.84	26.13 ± 2.50	30.47 ± 1.46	0.001	0.001	0.001
Mean SDQ score	85.83 ± 13.25	21.50 ± 20.37	7.58 ± 5.93	0.001	0.001	0.021

UCLA: University of California and Los Angeles shoulder scale; SDQ: Shoulder disability questionnaire.

When the groups were compared, no difference was found in the comparisons made at 6th week after treatment and at the 24th week after treatment (Table 4).

4. Discussion

In this study, it was aimed to evaluate if addition of ultrasound treatment to TENS, hot pack and exercise therapies provided additional contribution in treatment of adhesive capsulitis and it was found that physical treatment modalities provided improvement in clinical and functional status in adhesive capsulitis, but ultrasound had no additional contribution to this status.

In the study of Mao et al. [12] in which the relation between increase in joint range of motion and joint space capacity on arthrography was evaluated, the pos-

Table 4
Comparisons of evaluation parameters pre-treatment, post-treatment 6th and 24th week between the two groups

	Physical Therapy + Therapeutic ultrasound group	Physical Therapy + Sham ultrasound group	p
Resting pain			
Pre-treatment	2.80 ± 2.48	3.53 ± 2.61	0.422
6th week	0.60 ± 1.45	1.53 ± 3.91	0.634
24th week	0.00 ± 0.00	0.06 ± 0.26	0.317
Activity pain			
Pre-treatment	8.40 ± 2.06	6.93 ± 2.15	0.072
6th week	2.80 ± 2.11	3.33 ± 4.01	0.833
24th week	1.00 ± 1.00	1.20 ± 1.21	0.702
Active abduction (degree)			
Pre-treatment	80.33 ± 9.35	78.00 ± 13.34	0.583
6th week	118.00 ± 25.69	129.33 ± 30.76	0.283
24th week	145.67 ± 30.23	145.00 ± 25.63	0.949
Active flexion (degree)			
Pre-treatment	110.00 ± 14.88	102.00 ± 12.78	0.126
6th week	140.80 ± 11.51	142.33 ± 14.50	0.751
24th week	154.00 ± 9.86	154.67 ± 13.56	0.879
Active internal rotation (degree)			
Pre-treatment	28.00 ± 10.29	27.00 ± 10.82	0.771
6th week	45.67 ± 18.89	45.67 ± 18.31	1.000
24th week	55.00 ± 14.52	55.67 ± 17.91	0.912
Active external rotation (degree)			
Pre-treatment	19.33 ± 11.73	25.00 ± 11.49	0.208
6th week	41.33 ± 18.66	52.33 ± 10.63	0.052
24th week	62.00 ± 18.00	70.00 ± 12.95	0.173
Mean UCLA score			
Pre-treatment	12.73 ± 1.94	12.33 ± 1.84	0.567
6th week	25.53 ± 3.70	26.13 ± 2.50	0.611
24th week	29.93 ± 2.02	30.47 ± 1.46	0.413
Mean SDQ			
Pre-treatment	82.92 ± 16.45	85.83 ± 13.25	0.597
6th week	30.42 ± 22.14	21.50 ± 20.27	0.261
24th week	7.97 ± 6.50	7.58 ± 5.93	0.865

UCLA: University of California and Los Angeles shoulder scale; SDQ: Shoulder disability questionnaire.

itive effects of use of deep heater in adhesive capsulitis were examined. The patients were treated with passive mobilization, stretching and strengthening exercises in addition to short-wave diathermy or ultrasound (1 MHz, 0.8–1.2 W/cm^2, 8 min) for 4–8 weeks. At the end of treatment, it was shown that significant increase in joint range of motion was also compatible with arthrographic findings.

Gursel et al. [20] investigated the effectiveness of ultrasound treatment added to physical therapy and exercise program in 40 patients who had soft tissue pathology in the shoulder. Physical therapy was given to both groups (in combination with hot pack, interferential current and exercise). Therapeutic ultrasound was applied to one group and sham ultrasound was applied to the other group. Pain, ROM, health assessment questionnaire (HAQ), shoulder disability questionnaire were significantly improved in both groups after three weeks. No difference was found in this study in which early results were reported with evaluation performed immediately after treatment.

Dogru et al. [8] investigated the effectiveness of ultrasound (3 MHz, 1.5 W/cm^2, 10 min) and sham ultrasound in patients with adhesive capsulitis and evaluated the patients before treatment, after treatment and at the 3rd month. Improvement was found in pain, range of motion, shoulder pain and disability index and SF-36 values in the study in which hot pack application was performed in addition to ultrasound in both groups. The authors concluded that ultrasound treatment was not different from placebo in treatment of adhesive capsulitis.

Robertson and Baker [14] could find reliable evidence indicating that active ultrasound was more effective compared to sham ultrasound in treatment of pain and movement limitation only in 2 studies in an article in which they evaluated and compiled randomized, controlled effectiveness studies in terms of methodological compatibility and outcomes. These studies investigated the effectiveness of ultrasound in calcific tendinitis and carpal tunnel syndrome. Robertson and Baker noted that the ultrasound doses used were extremely variable and scientific data for dose selection in clinical practice were insufficient. The finding that US treatment used with two different frequencies did not provide additional contribution to the other physical therapy applications in the study of Dogru et al. [8] and in our study which were conducted specifically for adhesive capsulitis is a significant clinical result.

In the review of Tarang and Sharma [9] which included 39 studies in which the effectiveness of physical therapy agents in adhesive capsulitis was examined, it was reported that deep heaters could be used in reducing pain and increasing ROM and use of ultrasound was not effective in improving pain, range of motion and function. In the study of Speed [15] in which the therapeutic effects of ultrasound in soft tissue lesions were reviewed, it was noted that ultrasound had lack of clinical evidence of effect, though its physiological effects were demonstrated clearly in laboratory studies. Errors in the study design (inadequate blindness, insufficient number of samples, variable outcome measurements, insufficient follow-up period, presence of different pathologies in the study groups, differences in the ultrasound dose applied), errors in calibration of the machine, differences in the intermediates used have been proposed as the possible causes for this ineffectiveness.

Again in another review, Windt et al. [21] evaluated 38 studies for the effectiveness of ultrasound treat-

ment in musculoskeletal diseases and concluded that ultrasound was not effective in shoulder diseases. They also stated that they could not find any evidence indicating that therapeutic ultrasound in combination with exercise treatment had additional clinical contribution compared to exercise alone or sham ultrasound + exercise.

In the study conducted by Ainsworth et al. [22] to evaluate if ultrasound had any contribution to pain and quality of life, sham or real ultrasound was applied in addition to exercise and manual therapy in 221 patients who were divided into two groups. Although improvement occurred in pain, shoulder disability and quality of life criteria in both groups, no significant difference was found between the groups.

Heijden et al. [23] divided patients with shoulder pain and limitation into 5 treatment groups as (1) active interference and active ultrasound, (2) active interference and active sham ultrasound, (3) sham interference and active ultrasound, (4) sham interference and sham ultrasound and (5) no addition treatment in addition to exercise therapy and concluded that both interference and ultrasound did not make a contribution to exercise treatment for shoulder diseases, because they could not find any significant difference in the groups who were followed up for up to 12 months.

The primary treatment in adhesive capsulitis is conservative treatment [24,25]. The results of the studies on using of physical therapy modalities on the adhesive capsulitis are generally has lack of evidence. Combined use of physical therapy modalities rather than individually, is a more preferred method in clinical practice [26,27]. Active-passive range of motion exercises, stretching, proprioceptive neuromuscular fascilitation techniques are formed of basis of the treatment and recommended [24–26].

Although lack of therapeutic and sham ultrasound group alone was a limitation of our study, we preferred to reduce pain by analgesic current and to increase ROM by exercise because of presence of intensive pain in phase 2. Since we prefer combined treatment in clinical practice, it can be said that the results of the study can be used in daily practice. Also non-questioning of the analgesic requirement can also be considered as a limitation. The fact that the US instrument has not been calibrated is also a limitation.

In conclusion, it was observed that combination of physical therapy modalities was effective in improving pain, limitation of mobility and functional status in treatment of adhesive capsulitis, but addition of ultrasound treatment to these treatment modalities did not provide additional contribution in our study.

Conflict of interest

None to report.

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