

Adding Ultrasound in the Management of Soft Tissue Disorders of the Shoulder: A Randomized Placebo-Controlled Trial

Background and Purpose. There is still a lack of evidence about the beneficial effects of ultrasound (US) intervention for the management of soft tissue problems. Thus, this study was designed to assess the effectiveness of US over a placebo intervention when added to other physical therapy interventions and exercise in the management of shoulder disorders. **Subjects and Methods.** Forty patients who were diagnosed by ultrasonography or magnetic resonance imaging to have a periarticular soft tissue disorder of the shoulder were randomly assigned to either a group that received true US (n=20; mean time since onset of pain=8.7 months, SD=8.8, range=1–36) or a group that received sham US (n=20; mean time since onset of pain=8.1 months, SD=10.8, range=1–42). Besides true or sham US (10 minutes), superficial heat (10 minutes), electrical stimulation (15 minutes), and an exercise program (15–30 minutes) were administered to both groups 5 days each week for 3 weeks. **Results.** Subjects showed within-group improvements in pain, range of motion, Shoulder Disability Questionnaire scores, and Health Assessment Questionnaire scores with the intervention, but the differences did not reach significance when compared between the groups. **Discussion and Conclusion.** The results suggest that true US, compared with sham US, brings no further benefit when applied in addition to other physical therapy interventions in the management of soft tissue disorders of the shoulder. [Kurtaiş Gürsel Y, Ulus Y, Bilgiç A, et al. Adding ultrasound in the management of soft tissue disorders of the shoulder: a randomized placebo-controlled trial. *Phys Ther.* 2004;84:336–343.]

Key Words: *Physical therapy, Randomized clinical trial, Shoulder, Soft tissue disorders, Ultrasound.*

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Shoulder pain is a major reason that patients seek consultations with physicians. Pain restricts shoulder motion and limits daily activities, causing disability.^{1,2} In general, soft tissue impairments and pathologies such as inflammation of the tendons and bursae surrounding the glenohumeral joint are often diagnosed even in patients without a history of trauma.³ Management of these patients includes the use of analgesics and nonsteroidal anti-inflammatory drugs (NSAIDs), steroid injections, thermal modalities, ultrasound (US), and exercise programs. Systematic reviews of clinical trials on shoulder disorders show little benefit from NSAIDs and steroid injections.^{4,5}

Ultrasound is used as a therapeutic modality for many conditions in many countries⁶ and for soft tissue disorders. When US enters the body, it can exert effects on the cells and tissues via thermal and nonthermal mech-

anisms, of which some are still inconclusive.^{6,7} Ultrasound is believed to differ from superficial heating modalities by heating deeper tissues when applied with appropriate intensity and frequency.⁶ Nonthermal effects are claimed to promote healing, although this has not been proven with in vivo studies.⁷ Systematic reviews of clinical trials on shoulder disorders have shown US to be ineffective in achieving success in the intervention.⁸⁻¹¹ The effect of US in the management of soft tissue disorders of the shoulder was found to be of little or no clinical benefit in some studies.^{12,13} Some studies,¹⁴⁻¹⁶ however, have shown US to be effective in improving the symptoms. In our experience and contrary to the published data, US seems to be of some value in the management of shoulder problems. These conflicting results led us to plan this placebo-controlled study. The aim of our study was to evaluate whether US,

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Dr Kurtaiş Gürsel and Dr Dinçer provided concept/idea/research design. Dr Kurtaiş Gürsel and Dr van der Heijden provided writing. Dr Kurtaiş Gürsel, Dr Ulus, and Dr Bilgiç provided data collection, and Dr Kurtaiş Gürsel provided data analysis. Dr Kurtaiş Gürsel, Dr Ulus, Dr Bilgiç, and Dr Dinçer provided subjects. Dr Kurtaiş Gürsel and Dr Dinçer provided project management. Dr Kurtaiş Gürsel and Dr Ulus provided facilities/equipment. Dr Dinçer provided institutional liaisons. Dr Ulus was responsible for patient assessment and provided clerical support. Dr van der Heijden provided consultation (including review of manuscript before submission).

The study protocol was approved by the ethics committee of the İbn-i Sina Hospital, University of Ankara.

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when combined with hot packs and interferential current, enhances the outcomes of intervention.

Method

Subjects

Patients with soft tissue disorders of shoulder were considered for the study from the outpatient clinic and examined by the researchers, who are all senior physical medicine physicians. Physical, laboratory, and radiological examinations were used to confirm the diagnosis and rule out other conditions. The following selection criteria were used in our study:

1. Shoulder pain and limitation of movement for at least 4 weeks prior to the study (to eliminate acute pain that may recover quickly and spontaneously after a few physical therapy sessions).
2. Diagnosis of a soft tissue disorder of the shoulder (eg, bicipital tendinosis, rotator cuff tendinosis [including rotator cuff tears], subacromial bursitis) by ultrasonography or magnetic resonance imaging (through which calcific tendinitis was excluded).
3. Absence of direct trauma to the shoulder or the memory of trauma (to exclude probable fractures or resorbing hematoma).
4. Absence of underlying neurologic, inflammatory rheumatic disease, notably rheumatoid arthritis, systemic lupus erythematosus, or extrinsic diseases such as cervical spondylosis with referring pain to the shoulder. These other diseases were ruled out by physical examination and further laboratory examinations whenever needed.
5. No physical therapy for the shoulder was given in the 4 to 5 weeks prior to the study.

Forty patients who fulfilled the selection criteria and signed informed consent statements were enrolled in the study and were randomly assigned by the use of random numbers to either a group that received true US or a group that received sham US. The selector (GD), who did not perform any assessment, was aware of the randomization scheme and opened the codes at the statistical evaluation stage. The assessor (YU) and the subjects, however, were not informed about the true nature of US application. The treating physical therapist was aware of the nature of this intervention and the physical findings of the subjects, but did not change the intervention according to the symptoms during the study. Two subjects (one from each group) withdrew for personal reasons at the beginning of the study. The

Table 1.
Demographic Characteristics of Subjects

	True-Ultrasound Group (n=19)	Sham-Ultrasound Group (n=19)
Age (y)		
\bar{X}	54.16	54.00
SD	8.22	9.80
Range	38–69	35–69
Time since onset of pain (mo)		
\bar{X}	8.68	8.11
SD	8.84	10.81
Range	1–36	1–42
Sex (female/male)	12/7	14/5
Diagnosis (n)		
Supraspinatus tendinosis	6	6
Supraspinatus partial rupture	11	7
Rotator cuff rupture	1	3
Biceps tendinosis	8	7

demographic characteristics of the remaining 38 subjects are shown in Table 1.

Procedure

The true-US group received continuous US using a Petsan 250 device* that, according to the manufacturer, operated at a frequency of 1 MHz and at an intensity of 1.5 W/cm². The transducer head had an area of 6.2 cm², an effective radiating area of 5 cm², and a beam non-uniformity ratio of 1:6. While sitting on a table, each subject placed an arm with the hand supinated in his or her lap. Using slow circular movements, the treating physical therapist applied the transducer head over the superior and anterior periarticular regions of the subject's glenohumeral joint, covering an area of approximately 15 cm². The treatment duration was 10 minutes. For the sham-US intervention, the device was set to the "off" mode. The transducer head was applied to the same area using the same machine, and Aquasonic transmission gel[†] was used.

All patients had pain and limitation of motion; therefore, we did not believe we could treat the sham-US group without additional interventions. Other physical therapy interventions were applied to subjects in both groups. Superficial heat was administered by use of hot packs (60°C) for 10 minutes. Interferential current was delivered using Medi-Link Model 71,[‡] which operated with a carrier frequency of 4,000 Hz, with an amplitude-modulated frequency of 100 Hz. Rubber bipolar plate electrodes (6×8 cm) were placed again over the supe-

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rior and anterior periarticular regions of the glenohumeral joint. The intensity was set according to the sensory threshold level of each patient, and the treatment duration was 15 minutes.

Exercise for the shoulder girdle included the active and passive range of motion (ROM) exercises, stretching, Codmann exercises, and isometric and isotonic exercises. The exercises were applied to all of the subjects by the same physical therapist. The duration of exercise was a minimum of 15 minutes and a maximum of 30 minutes. At the start of the therapy, or when a subject had severe pain, passive restricted ROM exercises and gentle stretching were used. At a later phase or when pain lessened, exercise shifted toward active ROM exercises, and gradually isometric and dynamic resistance exercises were added, resulting in a longer duration of intervention.

The duration of physical therapy intervention was 15 days (5 days each week), which is the usual treatment regimen in our department's practice. The treatment protocol was not changed during the study in order to standardize intervention for all subjects. After the study period ended, the subjects' physical therapy interventions were changed, if needed. The subjects were not allowed to take medications other than a simple analgesic (paracetamol, maximum of 500–1,000 mg daily due to their pain).

Outcome Measures

Pain intensity at rest and with motion was measured using a 4-point Likert scale (0=no pain, 1=mild pain, 2=moderate pain, 3=severe pain). Passive and active ROM in flexion, extension, abduction, adduction, and medial (internal) and lateral (external) rotation was measured using a goniometer. All of the measurements were done while the subjects were positioned supine except for ROM in extension, which was measured while the subjects were sitting erect in a chair. Before the study began, the assessor (YU) performed repetitive goniometric measurements of the shoulder joints of 10 subjects with no known pathology or impairments to enhance the reliability of her assessment, but no other reliability study was performed. The Health Assessment Questionnaire (HAQ)¹⁷ was used to assess activities of daily living, and only items regarding upper-extremity function were included. The HAQ was shown to be sensitive for detecting changes in patients with rheumatoid arthritis and patients who had undergone joint replacement surgery, but no further studies have been done to evaluate the sensitivity of the tool in patients with shoulder disorders.^{18,19} Shoulder disability was assessed with the Shoulder Disability Questionnaire (SDQ), which was shown to be responsive to changes in symptoms and physical findings.^{20,21} When the study began

and on the day following the last day (15th day) of intervention, the same physician (YU), who was masked to the randomization, took all of the measurements.

Data Analysis

Differences between baseline and postintervention measurements for each studied outcome were analyzed within and between the groups. Repeated measurements obtained before and after intervention were analyzed within groups by a Wilcoxon rank sum test. Postintervention changes in categorical data within groups were analyzed by chi-square test with Yates correction. Between-group comparisons of differences after intervention were performed by a Mann-Whitney *U* test at a .05 level of significance.

Results

Seventeen subjects (89%) in the true-US group and 16 subjects (84%) in the sham-US group completed the 15-day intervention program. One subject from the true-US group and 1 subject from the sham-US group withdrew from the study because they could not spare time for the physical therapy sessions. Another subject from the true-US group and 2 other subjects from the sham-US group withdrew without any explanation.

Baseline and postintervention measurements are displayed in Table 2. No differences between groups were observed in the baseline measurements, and variability was relatively limited for almost all measurements; that is, standard deviations of the observed means of the changes over time were relatively small. For the true-US group, there were preintervention-postintervention differences for pain, ROM (except for passive abduction), and HAQ and SDQ scores. For the sham-US group, improvement was detected for pain, ROM (except for passive lateral rotation), and HAQ and SDQ scores. The preintervention-postintervention differences in the measurements, however, did not show any statistical difference between groups (Tab. 3).

Discussion

In the management of soft tissue disorders, US has been used for more than 30 years.^{22,23} Increased blood flow, vascular permeability, and cell metabolism; enhancement of fibrous tissue extensibility; and muscle relaxation are the purported physiologic effects of US. Ultrasound is proposed to promote healing and regeneration in inflamed tissue, to reduce pain, and to improve ROM,^{24,25} and this is the rationale for the use of US for the management of soft tissue disorders in all joints, including the shoulder. In our experience, US is commonly prescribed in addition to other interventions such as electrical stimulation and exercise. We used interferential current in our study because it is believed by some authors^{26–28} to have analgesic effects, but these effects

Table 2. Assessment Parameters of True-Ultrasound and Sham-Ultrasound Groups Before and After Intervention

Variable ^a	True-Ultrasound Group (n=17)						Sham-Ultrasound Group (n=16)							
	Before Intervention			After Intervention			Before Intervention			After Intervention				
	X̄	SD	Range	X̄	SD	Range	X̄	SD	Range	X̄	SD	Range	P	
Pain rating (on 0-3 Likert scale)														
At rest	2.4	0.5	1-2	1.0	0.1	1-1	1.8	0.7	1-3	1.3	0.4	1-2	.007 ^b	
With motion	2.4	0.5	2-3	1.9	0.2	1-2	2.7	0.4	2-3	2.1	0.2	2-3	.001 ^b	
Flexion														
AROM (°)	127.6	4.9	80-160	156.4	12.6	120-170	123.7	24.3	90-160	160.3	12.0	140-180	.0001 ^b	
PROM (°)	145.3	24.0	100-180	168.2	11.7	130-180	149.1	18.9	110-175	172.8	10.3	150-180	.0001 ^b	
Abduction														
AROM (°)	105.5	29.4	60-155	150.2	20.0	100-180	113.4	37.0	60-180	162.2	16.7	120-180	.001 ^b	
PROM (°)	127.3	25.4	80-165	160.6	16.7	120-180	141.5	25.9	100-180	174.4	10.7	140-180	.001 ^b	
Lateral rotation														
AROM (°)	65.8	4.0	20-70	81.4	15.5	30-70	74.1	22.7	20-70	87.8	5.4	60-70	.012 ^b	
PROM (°)	77.3	17.9	40-70	84.7	12.1	40-70	82.5	16.9	40-70	89.3	2.5	70-70	.066	
Medial rotation														
AROM (°)	48.2	4.0	20-60	71.4	18.7	40-60	52.8	22.8	20-70	72.2	13.4	50-70	.001 ^b	
PROM (°)	68.2	20.5	30-60	80.6	15.3	50-60	74.1	17.2	40-70	88.1	7.5	60-70	.007 ^b	
Extension														
AROM (°)	43.5	9.9	30-60	51.7	9.0	35-60	45.6	11.5	30-65	57.2	7.9	45-65	.001 ^b	
PROM (°)	55.0	7.0	40-65	57.9	8.1	40-70	56.8	6.3	45-65	60.3	6.1	50-70	.01 ^b	
HAQ	1	0.5	0.2-2.5	0.3	0.2	0-0.8	1.2	0.5	0.6-2.5	0.4	0.2	0.1-0.8	.0001 ^b	
SDQ	76.1	11.7	46-100	41.5	20.3	6-80	75.0	11.8	40-100	38.2	15.6	4-73	.0001 ^b	

^a AROM=active range of motion, PROM=passive range of motion, HAQ=Health Assessment Questionnaire, SDQ=Shoulder Disability Questionnaire.

^b Statistically significant difference (statistical level of significance: .05, Wilcoxon signed ranks test).

Table 3.

Change Over Time in Measurements From the True-Ultrasound and Sham-Ultrasound Groups

Variable ^a	True-Ultrasound Group (n=17)			Sham-Ultrasound Group (n=16)			P ^b
	Preintervention-Postintervention Difference			Preintervention-Postintervention Difference			
	\bar{X}	SD	Range	\bar{X}	SD	Range	
Pain rating (on 0–3 Likert scale)							
At rest	0.7	0.4	0–1	0.5	0.6	0–2	.36
With motion	0.4	0.5	0–1	0.6	0.4	0–1	.21
Flexion							
AROM (°)	29.4	23.6	0–70	36.5	25.5	5–90	.39
PROM (°)	22.9	20.1	0–60	23.7	16.4	5–60	.87
Abduction							
AROM (°)	44.1	24.6	10–90	48.7	29.9	0–100	.65
PROM (°)	33.2	22.7	5–80	32.8	26.3	0–80	.85
Lateral rotation							
AROM (°)	15.5	16.9	0–50	13.7	18.3	0–50	.69
AROM (°)	7.4	12.0	0–40	6.8	15.3	0–50	.45
Medial rotation							
AROM (°)	24.4	17.1	0–70	28.7	17.3	0–55	.28
PROM (°)	14.7	16.1	0–60	14.1	16.0	0–50	.79
Extension							
AROM (°)	10.0	8.4	0–25	11.5	8.1	0–25	.55
PROM (°)	4.1	6.6	0–25	3.4	6.2	0–25	.82
HAQ	0.6	0.5	0.1–2.3	0.8	0.5	0.2–2.3	.27
SDQ	34.5	19.0	1–12	36.7	18.1	1–12	.71

^a AROM=active range of motion, PROM=passive range of motion. HAQ=Health Assessment Questionnaire, SDQ=Should Disability Questionnaire.

^b Statistical level of significance: .05, Mann-Whitney *U* test.

are yet to be determined because of the inconclusive results obtained by other researchers.^{29,30}

In our study, US was applied in addition to the use of superficial heat because of the often-used hypothesis that US further affects healing in people with soft tissue diseases. Our study did not allow us to determine whether the heating effect of US was masked by the application of superficial heat. The results of our masked study demonstrated that at the end of the intervention period, our subjects with soft tissue disorders of the shoulder showed improvements in pain, ROM, and HAQ and SDQ scores when either true US or sham US was administered in addition to superficial heat, interferential current, and exercise, but neither group was compared with a group that received no intervention. Our groups were similar after randomization, with few dropouts, and there were no differences between the groups at our short-term follow-up. Whether the changes we observed would remain over time cannot be determined.

In a systematic review of randomized clinical trials for patients who received physical therapy for soft tissue disorders of the shoulder, 6 trials on the effects of US were found to be of acceptable methodological quality.⁸

However, US did not seem to be effective in placebo-controlled trials and was no better than cold therapy, steroid injections, NSAIDs, acupuncture, or transcutaneous electrical stimulation. In another systematic review, van der Windt et al⁹ showed a lack of sufficient data to support positive results about the effectiveness of US for musculoskeletal disorders, including soft tissue problems of the shoulder.

Several authors^{12,13,31} have reported that there were no differences between subjects with soft tissue disorders of the shoulder who received true US and those who received sham US. Studies by other researchers^{14–16} support the efficacy of US therapy in improving pain, activities of daily living, and quality of life. The subjects in these studies varied from another. For instance, Ebenbichler et al,¹⁵ who reported no effects of US on pain and disability in the long term, found changes in the calcific deposits of their subjects with calcific tendinitis of the shoulder. We excluded patients with calcific tendinitis of the shoulder in our study; therefore, our study is not comparable to that of Ebenbichler et al.

Despite various suggestions provided in classical textbooks on physical treatments,^{24,25} there is no accepted standardized method for US application. Yet, although

there is no evidence from well-designed studies that one method of application outperforms another, we cannot be sure which method is the best. Treatment intensity, duration, and frequency and localization of US application were not the same in all the trials cited. In 2 studies,^{13,14} the frequency of US was the same as in our study (1 MHz). Commonly, US is applied as a co-intervention. The co-interventions in the cited studies also were very different. Ginn et al³² reported that subjects who received a program of exercise aimed at restoring force, length, and control of muscles demonstrated better outcomes than did subjects who received no intervention. A comparison of groups that received either true or sham US with a group that did not receive US, however, did not show results favoring the use of US, either on short- or long-term follow-up.¹² A recent overview of research on shoulder disorders has shown that evidence for an effect of physical therapy on the long-term outcome of shoulder disorders is lacking.³³

The results of our study showed that there were no differences between the outcomes of 2 groups. Our study provided no evidence that true US, as compared with sham US, is beneficial when applied in addition to some commonly used interventions, including modalities such as exercise therapy. This result seems to be in concordance with the findings of many other studies. Due to our small sample size, however, our results lack statistical power. In addition, the between-group differences were too small to be clinically relevant. Given the lack of between-group differences at short-term follow up, it is unlikely that with evaluation of effects at a longer term an effect in favor of true US would be observed.

Conclusion

Based on the literature and the results of our study, we conclude that there is insufficient evidence to merit wide use of 1-MHz US in combination with other interventions in the management of painful shoulder conditions. In our opinion, with the guidance of randomized controlled trials, it is time to use interventions that favor minimal use of time and maximum economy. Although further studies are needed on the effectiveness of physical therapy interventions in the management of painful conditions such as shoulder disorders, it is apparent that adding US to a well-planned intervention regimen has no benefit. We believe future research should consider comparisons of interventions with painkillers, NSAIDs, steroid injections, or even the use of a wait-and-see policy.

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