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The Importance of Night Pain for the Effectiveness of Theurapotic Ultrasound in the Sub acromial Impingement Syndrome: A Randomized Controlled Trial

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Abstract

Objective: The aim of this study is to assess the importance of night pain for the effectiveness of therapeutic ultrasound in treating Subacromial Impingement Syndrome (SIS).

Methods: In this double-blind, placebo controlled study, patients with SIS accompanying with night pain were evaluated. The cases were divided as A and B groups randomly. Group A, received standard conservative treatment and additional ultrasound or placebo ultrasound randomly while having night pain. On the other hand, group B, received cold application and same standard conservative treatment. When the night pain subsided, ultrasound or placebo ultrasound was given randomly. The cases were evaluated with visual analogue scale, shoulder disability index and Constant Murley functional assessment scale during follow ups.

Results: In group A, statistically meaningful improvement in resting, movement and night pain, disability and functionality were detected. However there were no statistically important differences between cases receiving ultrasound or placebo ultrasound. There were statistically important improvement in resting and movement pain, disability and fuctionality of group B cases. But with ceasing the cold application and starting either of ultrasound or placebo ultrasound, some increase in night pain was seen. There were no statistically important difference between ultrasound and placebo ultrasound.

Conclusion: Adding ultrasound to the standard conservative treatments in SIS patients with or without night pain makes no additional benefit.

Keywords: Shoulder pain; Therapeutic ultrasound; Night pain

Introduction

Night pain is a common symptom in shoulder pathologies. Also known as sleeping pain or pain at sleep, night pain is frequently associated with subacromial impingement syndrome (SIS), but its etiology is unclear [1].

Sleeping postures that increase sub acromial pressure, and the persistence and severity of the underlying pathology may exacerbate night pain. Inflammatory arthritis, infections which can also cause shoulder pathologies may also generate night pain [2]. As a result, night pain is important symptom from both diagnostic and treatment perspectives.

One physical modality commonly used to treat SIS is ultrasound. In the literature, there are lots of studies with various treatment options; some of them using one physical agent or combination of physical agents, others are placebo controlled or comparisons with each other [3-8]. In these studies, there are conflicting results about the effectiveness of ultrasound in the management of SIS. We noticed that these studies did not consider the presence of night pain during case selection.

It's known that inflammation causes night paint and sleep disturbance in lots of painful pathologies [9]. Because by the increment of severity of the pathology in SIS, night pain emerges; it is thought that patients with night pain have more inflammation and carries acute characteristics [2]. There is debate about the effectiveness of deep heaters like ultrasound in acute inflammation [10]. Therefore, in these chronic pathologies with frequent accompanying acute inflammatory episodes, the conflicting results of ultrasound may be due to presence of inflammation.

The aim of this study is to assess the importance of night pain for the effectiveness of therapeutic ultrasound in treating SIS.

Material and Methods

A total of 118 cases with shoulder pain that had been clinically diagnosed as SIS were evaluated. Among them, 57 cases that met the inclusion criteria were included to this double-blind and placebo-controlled study.

Case selection

The age, sex, and occupation of each patient were recorded. Pain characteristics and additional problems were also noted. Diagnoses

were based on history, clinical examinations, conventional radiography, and subacromial injection tests.

For subacromial injection test, 5 ml of 2% lidocaine was injected with anterolateral approach into the subacromial space in a sitting position [11,12]. Fifty percent decrease in pain and increase in the range of motion nearly to normal level after 1 hour of evaluation was accepted as positive test result.

Patients with a positive impingement test (Neer, Hawkins–Kennedy, and painful arc tests) and a positive subacromial injection test were diagnosed with SIS if they had no calcified lesions in plain radiograms. Shoulder ultrasonography was also performed by an experienced doctor (KA). After detailed clinical and radiological evaluation, cases meeting the following criteria were also excluded from the study:

- Patients under 30 years or over 60 years old.
- Patients whose major complaint was attributable to acromioclavicular pathology, or other primary shoulder disorders
- Cervical pain or other painful conditions that conflict with the clinical picture.
- Potentially serious pathologies (e.g., inflammatory arthritis, polymyalgia rheumatica, or malignancy).
- Neurological or vascular pathologies.
- Recent shoulder surgery.
- Recent history of shoulder trauma, fracture, or dislocation.
- Prior treatment with physiotherapy, corticosteroid injections, or NSAIDs during the preceding 3 months.
- Direct radiological identification of calcific lesions, glenohumeral osteoarthritis, or space-occupying lesions.
- Ultrasonographic findings of calcific lesions, full-thickness rotator cuff tear or space occupying lesions.

Treatment groups

All the patients were prescribed 15 mg of meloxicam and 30 mg of lansoprozol to use once a day during the first 1 month. They were instructed to avoid exaggerated movements of shoulder joint with a relative rest and to perform Codman's pendulum exercise (5 minute/5 times a day) in this time period. Shoulder positions of the patients during sleeping were questioned and they were instructed to sleep on unaffected shoulder or in a supine position and to support the painful shoulder with a pillow. Patients were divided as group A or B by block randomisation. Patients in group A were randomly assigned again to receive either 15 sessions of ultrasound (1.5 watt/cm^2 10 minute) (group A1) or placebo ultrasound (group A2) while having night pain. On the other hand, patients in group B received cold application in addition to conservative treatments mentioned above. After the night pain subsided, they were randomly assigned again to receive either 15 sessions of ultrasound (1.5 watt/cm^2 10 minute) (group B1) or placebo ultrasound (group B2). In this double blind and placebo controlled study, neither the doctor nor the patients knew which treatments were being given. The placebo ultrasound group received the same duration of apparent treatment with the machine switched on but no output, to blind the control patients.

Outcome evaluation

Both groups were evaluated before treatment, and patients in group A were evaluated on day 10, day 15 and 1 and 3 months after ultrasound or placebo ultrasound treatment. Because the patients in group B received conservative and cold treatments before electrotherapy, they were evaluated again after their night pain subsided. Following the start of ultrasound or placebo ultrasound treatment, these patients were evaluated on day 10, day 15, and 1 and 3 months after treatment. At each visit, shoulder pain at rest and during activity, and pain that disturbed sleep were evaluated using a visual analogue scale (VAS). Patients were instructed to rate their pain intensity on a 10-point scale. Shoulder joint function was evaluated using the Constant scale and its sub-sectional parameters and the Shoulder Disability Questionnaire (SDQ). The Turkish version of the questionnaire and its assessment scale were valid and reliable.

Ethical Committee

This study was approved by institutional ethics committee and all participants provided informed consent.

Statistical Analysis

Changes in pain and functional parameters within and between the groups were evaluated by nonparametric analysis of variance (ANOVA), Mann-Whitney U and Wilcoxon's tests using SPSS software (ver. 22.0; SPSS, Inc., Chicago, IL, USA). A p-value of ≤ 0.05 was considered statistically significant.

Results

A total of 57 patients (41 females and 16 males) with SIS were included in this study; their mean body mass index (BMI) was 29.5, and mean age was 49.7 years. There were no significant ages, sex, BMI, or symptom duration differences among the groups (Table 1).

Treatment	Age	Gender	Height	Weight	BMI	Total Number
Groups	Mean+SD	F/M	Mean+SD	Mean+SD	Mean+SD	
A1	47.3 ± 7.9	14/2	160.4 ± 4.7	75.0 ± 10.7	29.0 ± 3.5	16
A2	52.6 ± 7.1	8/4	163.8 ± 7.2	83.0 ± 8.8	30.9 ± 3.4	12
B1	49 ± 8.4	9/5	163.9 ± 8.3	77.3 ± 9.5	28.7 ± 2.8	14
B2	50.4 ± 6.8	10/5	162.6 ± 8.0	78.0 ± 10.7	29.5 ± 4.1	15
Total	49.7 ± 7.7	41/16	162.5 ± 7.1	78.0 ± 10.2	29.5 ± 3.5	57

Table 1: Demographic Information.

Group A consisted of 28 patients who were randomized into ultrasound (n=16; group A1) or placebo ultrasound (n=12; group A2) treatment groups. Group B consisted of 29 patients who initially received the cold and conservative treatments. After night pain had subsided, these patients were randomized into ultrasound (n=14; group B1) or placebo ultrasound (n=15; group B2) treatment groups. Following conservative treatment, two patients from group B1 and two patients from group B2 had no shoulder problem and were excluded from the study. Therefore, a total of 12 and 13 patients formed groups B1 and B2 respectively. The average time ± standard deviation from the beginning of conservative treatment to the initiation of either ultrasound or placebo ultrasound was 15.4 ± 2 days.

Baseline values of pain measured by VAS, the total and subsection scores obtained using the Constant scale and SDQ were all comparable among the groups (p>0.05) (Table 2).

Before treatment	Resting Pain	Movement Pain	Night Pain	Total Constant Score	SDI Mean ± SD	Total Number
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
A1	4.0 ± 2.4	8.0 ± 2.0	7.7 ± 2.2	59.3 ± 4.9	85.4 ± 17.0	16
A2	4.5 ± 2.8	8.0 ± 2.0	7.0 ± 2.6	63.6 ± 9.8	72.3 ± 27.8	12
B1	4.3 ± 1.8	8.0 ± 2.0	7.7 ± 2.3	62.2 ± 8.2	76.1 ± 21.7	14
B2	3.8 ± 2.4	6.9 ± 2.2	6.8 ± 2.0	65.8 ± 6.6	71.0 ± 20.4	15
Total	4.1 ± 2.3	7.7 ± 2.1	7.3 ± 2.2	62.6 ± 7.6	76.3 ± 21.4	57

Table 2: Baseline values of pain, the total and subsection scores obtained using the constant scale and shoulder disability questionnaire.

Compared with the baseline values, a significant improvement in all pain parameters using the VAS and in the total and subsection scores obtained using the Constant scale and SDQ, was observed in the group A follow-up visits. However, no significant differences were observed between group A1 and A2.

Compared with the baseline values, significant improvements in pain while resting and during activity measured using the VAS, and in the total and subsection scores obtained using the Constant scale and SDQ, were observed in group B follow-up visits. However, stopping the cold treatment and starting the ultrasound or placebo ultrasound treatment led to an increase in night pain (Figure 1). The statistically significant differences in clinical improvement and increases in night pain scores were observed in groups B1 and B2.

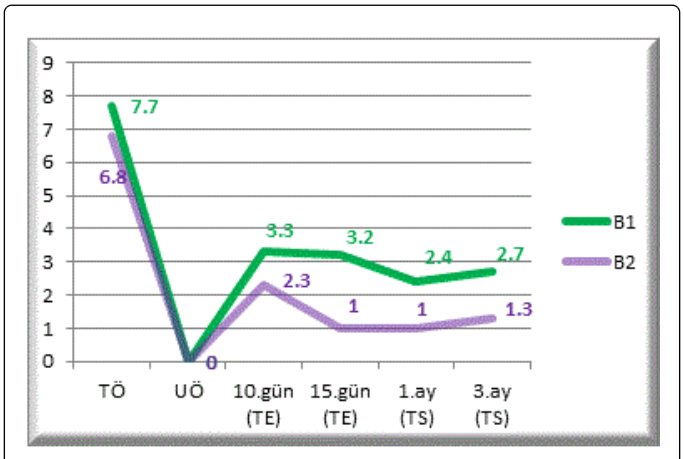

Figure 1: The change of night pain during the study in group B1 and B2.

Discussion

The night pain, etiology of which couldn't be explained yet and known as sleeping pain or pain at sleep in the literature is frequently seen complaint in SIS and lowers the quality of life of the patients [1].

In this study, only patients with night pain were included. A total of 71.9% of them said that their pain keeps them awake at night and the others reported pain on awakening in the morning. Night pain is often reported by SIS patients [1,4,12,13]. A total of 20 patients with rotator cuff tears, questioned as part of a study, reported difficulty falling asleep and finding a comfortable sleeping position, that night pain wakes them up and that sleeping problems had prompted them to consult their doctor and was affecting their quality of life [1].

Patients usually reported that night pain. exacerbated by lying on the affected shoulder. or sleeping with the affected arm overhead [3]. Research on the four most common sleeping positions concluded that subacromial pressure on the rotator cuff is significantly reduced when patients sleep in a supine position compared with a prone or side position. Tendon perfusion which is adversely affected by subacromial pressure is crucial for tendon-to-bone healing. Therefore, avoiding sleep positions that increase subacromial pressure is an important part of SIS treatment [14]. All patients in our study were advised to sleep on the unaffected shoulder or in a supine position.

Although little is known about the causes of night pain in patients with shoulder pathologies, the duration and severity of the problems and the intensity of the pain may be important [2].

A study of 130 patients with shoulder pain found a statistically significant increase in the prevalence of sleep disturbance in patients with shoulder pain persisting for at least 3 months compared with a control group. They concluded that shoulder pain lasting 3 months or longer is a strong predictor of sleep disturbance and this reflects the commonly accompanying night pain in shoulder pathologies [15]. The average symptom duration in our study was 8.4 ± 2.1 months.

The present findings suggest a strong correlation between pain severity and sleep quality but the underlying mechanism of the

relationship of sleep disturbance or poor sleep quality with pain didn`t known yet exactly. However, there are some speculations in the literature that it might be related with biochemical changes in the brain [16]. Patients with SIS have significantly lower pain pressure thresholds than do controls in both local and distal areas from their affected arm consistent with primary and secondary hyperalgesia, respectively. Data suggest the presence of central sensitization among subjects with chronic SIS [17]. Sleep disturbance which is very frequently seen in chronic pain patients can increase pain perception. It's found in a study that one night of total sleep deprivation promotes a state of generalized hyperalgesia [18].

SIS treatment aims include relieving inflammation.,providing time for the rotator cuff to heal and improving shoulder function by reducing pain [19]. To accomplish these treatment goals, NSAIDs, rest various exercise programs, and physical treatments may be recommended at different stages of SIS management, as defined by Neer [12].

Ultrasound therapy was applied at 1.5 W/cm^2 intensity and 1 MHz frequency for 8 min and then adjusted according to patient tolerance. Levendoglu et al. also used the same dose and duration of ultrasound to treat SIS that we used in our study. They compared the efficacy of different treatment durations and demonstrated that ultrasound had beneficial effects on pain and shoulder function in SIS patients. They found that 8 min of ultrasound treatment was more effective than duration of 4 min [20].

There is substantial evidence to suggest that inflammation plays an important role in SIS pathogenesis [21]. A study that compared NSAIDs with placebo found that acute shoulder pain decreased within 1-2 weeks [22]. The effectiveness of corticosteroid injections also indicates that inflammation is involved in SIS pathology [9,13]. All patients included in our study were prescribed 15 mg of meloxicam and 30 mg of lansoprazole once per day during the first month of treatment.

It's well known for long years that cold application is effective in pathologies in which acute inflammation dominates. It decreases edema local blood flow, joint and intramuscular pressure and relieves pain [23]. The main physiologic mechanism responsible from these effects are vasoconstriction and then decrease in metabolic functions and slowing of sensory and motor nerve conduction indirectly [24]. Also by increasing the threshold of pain perception in nerve endings it produces analgesia [25].

To reduce the level of acute inflammation, patients with shoulder pathologies are advised to rest and restrict repeated movements of the shoulder that raise the arm overhead. Inflammation can trigger fibrin deposition and scar formation producing shoulder contracture [26]. Exercise therapy should begin as soon as possible because long periods of immobilization can have adverse effects on joint cartilage [27]. All of the patients in our study were asked to rest, but also to perform Codman's pendulum exercises from a very early stage [28].

Previous research on the effects of ultrasound on inflammation has produced differing results. Some studies have shown that ultrasound has anti-inflammatory effects on experimentally induced arthritis [29]. However, Goddard et al. tested ultrasound on a rat model of acute inflammation and observed no anti-inflammatory effects [11]. Some reports have even suggested that ultrasound may increase the level of inflammation [30].

A visual analog scale (VAS) was used to assess pain of all patients included in this study in resting activity and at night [31]. In a study, the smallest difference in an outcome score which a patient perceives as beneficial was found to be 1.4 and the score below which patients consider themselves well was 3 [32]. In our study, it's found that with combination of conservative treatment and ultrasound therapy, the pain scores decreased below 3 and the change in pain score was more than 1.4 in most of the patients and this improvement was statistically significant. But there wasn't any statistically significant difference between ultrasound and placebo ultrasound. In the group which received cold application until night pain evades, improvement in resting and activity pain was also detected. Also, in this group by stopping cold application and starting the either of ultrasound or placebo ultrasound increase in night pain was seen. This suggests that providing cold treatment in addition to conservative treatment is very beneficial during the SIS inflammatory stage and should be continued even after night pain subsides.

In addition to improved pain scores, our study recorded statistically significant improvements in the SDQ and Constant scale scores. However, we found no differences between the ultrasound and placebo ultrasound groups.

While waiting improvement of night pain in group B patients also improvement in resting and activity pain and improvement in SDQ and Constant scale was detected with combination of cold application and conservative treatment. Night pain was subsided after aproximately 15.4 days in group B patients receiving cold and conservative treatment. Because patients in group A were evaluated after 10 and 15 days after starting of ultrasound therapy, the results from the two groups could be compared at day 15. According to this comparison, it's found that night pain was better in group B in 15 day and the differences between groups were statistically significant. On stopping the cold treatment and starting either of ultrasound or placebo ultrasound therapy, night pain increased. This demonstrates the beneficial effects of cold treatment and the significance of inflammation in SIS pathology.

Studies on the efficacy of ultrasound therapy in treating SIS have produced conflicting results [5-9]. A large number of studies comparing ultrasound with other physical treatment modalities or with placebos have reported that it reduces shoulder pain during activity at rest and at night [5-8]. In contrast other studies have reported that treating shoulder pathologies with ultrasound is no more effective than using a placebo [9].

A study compared the effectiveness of low frequency laser and ultrasound; it's found that ultrasound therapy decreased night activity and resting pain in patients with SIS [6]. In another similar study which compare the same physical modalities mentioned above found that the group which received ultrasound therapy had statistically lower shoulder pain and disability scores and the improvement in sleep quality was better after treatment [7]. Because these studies are not placebo-controlled, the net effect of the ultrasound treatments could not be measured. In our study, the patients receiving ultrasound therapy in addition to conservative treatment had decreased shoulder pain, disability and functional scores. However, the decreases in these parameters did not differ significantly from those observed in the placebo ultrasound group.

A meta-analysis reported that ultrasound therapy was not effective in treating shoulder pathologies [9]. All treatment groups, including those patients receiving ultrasound therapy improved but did not differ

from the placebo groups. This meta-analysis demonstrates that studies on the effectiveness of ultrasound therapy have generated conflicting results and there is no mid to long-term study evidence [33]. However, the characteristics of the patients included in these studies were not recorded in detail, the differential shoulder pathology diagnoses were not reported precisely and the ultrasound treatment parameters differed among studies.

There is insufficient evidence from previous studies to conclude whether ultrasound therapy is effective. Most reviews investigating the effect of ultrasound agree that more studies are required to clarify the most suitable parameters and treatment protocols to use before concluding that ultrasound therapy is ineffective [34]. It is important to assess night pain and inflammation in painful shoulders before including ultrasound therapy in a rehabilitation program.

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