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ORIGINAL RESEARCH STUDY

Does ultrasound therapy add to the effects of exercise and mobilization in frozen shoulder? A pilot randomized double-blind clinical trial

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ABSTRACT

Objective: This study intended to determine the extent to which Ultrasound could add to the effects of exercise and manual therapy in the rehabilitation treatment of primary adhesive capsulitis.
Design: A pilot double blind randomized clinical trial was carried out on 50 patients suffering from primary adhesive capsulitis. Intervention included continuous 3 MHz, 1.5 w/cm^2 Ultrasound, applied for the first group and sham Ultrasound for the second group. In addition specific stretching and strengthening exercises as well as glenohumeral joint mobilization were delivered to both groups. Pain (VAS), functional ability (using Oxford Shoulder Score) and shoulder range of motion were assessed at the baseline, after 10 sessions of treatment, and at 3 months follow-up. An intention to treat Mixed ANOVA analysis was performed to explore the interaction effects of time and group on outcome measures.
Results: No significant interaction effect of time and group was seen on pain, function and Range of Motion ($p > 0.05$), meaning that the amount of improvement in all outcome measures were alike in the two groups.
Conclusion: Applying continuous Ultrasound along with a regimen of semi supervised exercise and mobilization in patients with primary adhesive capsulitis did not have any additional effect to the placebo Ultrasound, on outcome measures. Larger scale studies are needed to confirm the findings.

Introduction

Adhesive capsulitis or frozen shoulder is the self-limiting shoulder pain and dysfunction due to localized inflammation and fibrosis of the glenohumeral joint capsule which has 3 pathophysiological pathways: primary (idiopathic); Secondary that can be attributed to a known intrinsic, extrinsic, or systemic cause and; Tertiary which is post operative or post-fracture frozen shoulder (Shamus (2014); Brumitt, 2013). There are also new ideas suggesting that classification of adhesive capsulitis into two groups, "pain predominant" and "stiffness predominant", may be simpler and more appropriate (Russell et al., 2014).

It affects 2%–5% of the general population mostly between age 40–65 years old and mostly women (Cadogan and Mohammed, 2016; Shamus, 2014; Yoon et al., 2016).

Symptoms include pain especially with movement and significant loss of active and passive shoulder range of motion with external rotation presenting the greater loss in most cases followed by loss of abduction and internal rotation (Brumitt, 2013). These signs indeed have functional complications such as limitation in overhead activities, reaching, lifting, dressing etc. and it also may disrupt night sleep (Shamus, 2014). The most effective treatment for adhesive capsulitis is not established yet. Meanwhile the routine plan of care and intervention comprises surgical and non-surgical treatments (Alptekin et al., 2016; Cadogan and Mohammed, 2016; Favejee et al., 2011; Russell et al., 2014). Supervised neglect is shown to yield better outcomes versus intensive physical therapy in patients with adhesive capsulitis (Diercks and Stevens, 2004).

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Non operative interventions include oral steroids, corticosteroid and glucocorticoid injections and physiotherapy comprising of exercise therapy, mobilization and use of modalities (Brumitt, 2013; Cho et al., 2016). A review by Favejee in 2011 found strong evidence for the effectiveness of steroid injections in short-term and moderate evidence in mid-term follow-up. Moderate evidence was found in favor of the effectiveness of arthrographic distension alone and as an addition to active physiotherapy in the short term, for the effectiveness of oral steroids compared with no treatment or placebo in the short term, and for the effectiveness of SSNB (suprascapular nerve block) compared with acupuncture, placebo or steroid injections. For other commonly used interventions no or only limited evidence was found (Favejee et al., 2011).

A few high quality studies have shown that exercise plus mobilization have significant benefits on ROM in adhesive capsulitis (Celik, 2010; Page et al., 2014a, 2014b; Page and Labbe, 2010). The use of physical modalities ranging from electrical stimulations like TENS to superficial and deep thermal agents like hot pack and Ultrasound are primarily an adjunct to exercise and other treatment approaches in musculoskeletal physiotherapy. Even though electrotherapy modalities are used frequently in physiotherapy treatment of adhesive capsulitis, the evidence suggest that only low level laser therapy and pulsed electromagnetic field have been compared to placebo and that, no trial has compared electrotherapy modality plus manual therapy and exercise to manual therapy and exercise alone.Ultrasound is one modality which despite its use in patients with adhesive capsulitis has no evidence to its efficacy (Bélanger, 2015; Dogru et al., 2008; Page et al., 2014a).

The therapeutic effects of Ultrasound are classified as thermal and non thermal. Ultrasonic energy increases molecular motion which in turn, rises tissue temperature and affects tissue in different ways; such as changing nerve conduction velocity and increasing pain threshold, increasing collagen extensibility, increasing local blood flow and reducing muscle spasm. Nonthermal or mechanical effects of Ultrasound are the result of cavitation and microstreaming that can alter cell membrane permeability and thus facilitate soft tissue healing (Ebadi et al., 2013, 2014). The rational for using Ultrasound in patients with adhesive capsulitis can be affecting pain and specifically the viscosity of the collagen of the capsule (Page et al., 2014a).

To the best of our knowledge despite widespread use of ultrasound as part of the treatment regimen of adhesive capsulitis (Brumitt, 2013), there is no high quality research up to this date that has investigated the effect of real Ultrasound in comparison to the placebo Ultrasound on the outcomes in adhesive capsulitis. Therefore, the main objective of this pilot study was to evaluate the effectiveness of therapeutic continuous Ultrasound on pain, function and ROM of patients suffering from adhesive capsulitis in comparison to placebo ultrasound.

Materials and methods

Study design

This interventional study is a pilot longitudinal randomized double-blind (assessor, patient, and therapist) clinical trial. Ethics committee of Iran University of Medical Sciences approved the study (IR.IUMS.REC 1394.8621215541). The trial was carried out in one university hospital physiotherapy clinic (Firouzgar hospital, Tehran, Iran). Patients with the diagnosis of primary adhesive capsulitis were enrolled and asked to read and sign the consent form approved by the Vice chancellor for research, Iran University of Medical Sciences, covering full information about the trial and their rights.

Subjects

The inclusion criteria were: Age between 40 and 70; being diagnosed with primary idiopathic adhesive capsulitis; the involvement of only one side; shoulder pain and limitation of movements for at least 3 months prior to the study; No systemic diseases (diabetes, rheumatoid arthritis, etc.); no specific psychological disorder; patient has not received physiotherapy treatment during last 6 months and not using anti-pain medication during the study. Exclusion criteria included: patients not willing to continue the study anymore and noncompliance to any one of the inclusion criteria during the trial. After a thorough examination of patients by the informed physician and later again by the therapist in the physiotherapy clinic, 50 patients were enrolled for the study. The diagnoses was based on history taking, complete physical examination and ultrasonographic evaluation and after ruling out the secondary causes with radiographs and blood lab tests (Vuillemin et al., 2012). The patients were randomly allocated to 2 groups of real ultrasound therapy (continuous Ultrasound) and sham ultrasound therapy (sham Ultrasound) using randomly generated treatment allocations within sealed opaque envelopes generated by a statistician not involved in the recruitment.

Primary outcome measures

Pain and Oxford Shoulder Score questionnaire were measured before treatment, early after treatment, and after 3 months from the last treatment session.

We used the valid Persian version of the Oxford Shoulder Score which is a subjective questionnaire containing 12 questions on pain and function. The final score ranges from 12 (least difficulties) to 60 (most difficulties) (Naghdi et al., 2015).

The visual analogue scale (VAS) was used to assess shoulder pain intensity during last 2 days. A visual analogue scale is a valid means to measure pain intensity. It is a 100 mm horizontal line, where 0 mm indicates “No pain” and 100 mm indicates “Unbearable pain” (Ebadi et al., 2012).

Secondary outcome measure

Active Range of Motion (forward flexion, abduction, internal and external rotations) was measured with a standard universal goniometer (Fieseler et al., 2015; Kolber and Hanney, 2012; Lee et al., 2015).

Interventions

The real Ultrasound therapy group received continuous Ultrasound; 3 MHz, 1.5 w/cm^2 for 6 min on the anterior and posterior aspects of the glenohumeral capsule (3 min on an average area of 6 cm^2 on each side) using Sonopuls 492 (ENRAF Nonius, Netherlands). The Ultrasound head was moved circularly at a rate of around 3 cm/s.

Ultrasound unit was on for the sham group so as to have the light on, but the output was set at zero and the head was moved at the same pattern and for the same duration as for the real Ultrasound group. The Ultrasound device settings were adjusted by the physiotherapy assistant so as to keep the therapist and the patient (couldn't see the screen of the device) blinded.

Patients in both groups came to the clinic 3 times a week (every other day except for the weekends) for 10 sessions. Specific stretching and strengthening exercises for the shoulder were instructed and demonstrated by the physiotherapist on each session to both groups during the treatment period, starting from low magnitude to high level exercises. Also, each patient was provided

with a pamphlet containing the picture and the explanation for all the exercises to ensure compliance.

Exercises prescribed were as follows:

The exercise regimen began with stretching exercises for all sides around the shoulder including: pendulum stretch (passively); towel stretch behind the back to increase internal and external rotations; finger walk on the wall; using shoulder wheel; working on pulleys; stretching anterior capsule while standing next to the door and walking pass the door; cross body stretch for posterior capsule; stretch arm overhead with the help of the good arm in lying or standing.

Strengthening exercises included: isometric internal and external rotation progressed into active resistive with Theraband; holding and moving cane forward and backward (extension and forward flexion); triceps and biceps strengthening. Moreover, low grade Maitland glenohumeral mobilization plus PNF techniques (contract-relax) were performed on all patients from the 3rd session by the physiotherapist for increasing Range of Motion in all directions.

Levels of intensity were individualized for each patient and variations in repetition and resistance were applied. Patients were encouraged to keep their activity level high at home to a point that did not exacerbate pain and discomfort. Specific blank spaces were provided in the pamphlet next to each exercise and patients were asked to note down the number of repetitions they had performed, to check the rate of compliance (Bassett and Prapavessis, 2007). During follow up, patients were called by the physiotherapist assistance once a week to be reminded to perform the exercises according to the orders given by the therapist.

Statistical analysis

An intention to treat analysis was performed using SPSS V22, SPSS Inc., Chicago, IL, USA. Kolmogorov-smirnov test showed normal distribution of the data. In case of dropouts, last observation of the patient was used for the analysis (Last Observation Carried Forward (LOCF)). Independent *t*-test and Chi-square test were used to compare parametric and non-parametric data at baseline between groups.

Mixed ANOVA and post hoc tests were used to investigate the interaction effects of time and group on data. Greenhouse-Geisser estimates of sphericity were used to correct degrees of freedom wherever Mauchly's test was significant. Additional analyses were performed to break down the interaction effects, and contrasts were performed comparing each level of interaction during different time points. Results are reported at 95% confidence interval and the significancy was set at $p > 0.05$.

Results

The flow chart of participants is showed in fig. 1. From the initial 62 patients referred by the informed physician, a total of 50

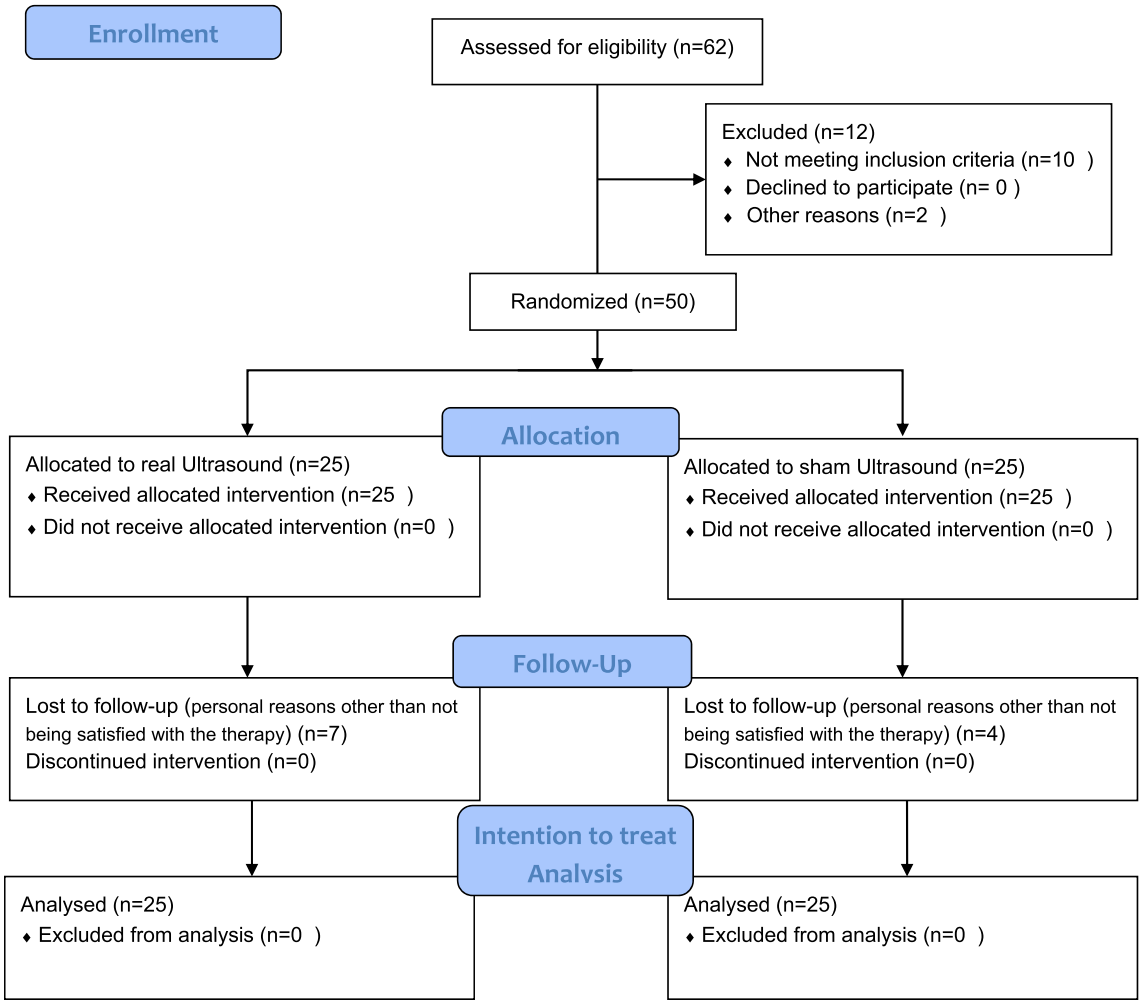

Fig. 1. CONSORT 2010 flow diagram.

patients were randomized into 2 groups after the final examination by the therapist. Patients aged around 49.74 (7) years and the mean symptom duration was 5.36 (1.9) months. Baseline characteristics of patients in both groups did not differ significantly $p > 0.05$ (table 1). Sixty percent of patients in both groups were women.

All outcome measures were equal at baseline between the 2 groups ($p > 0.05$) (table 2).

Two patients in the sham Ultrasound group and 3 patients in the real Ultrasound group did not participate in the after treatment measurements due to travelling. Four patients in the sham Ultrasound group and 7 patients in the true Ultrasound group did not come for follow-up assessments because of personal reasons other than not being satisfied with the therapy. No adverse events to treatment were reported (the patients who did not participate in the after 10 sessions measurements, also did not participate in the follow up assessment).

VAS and functional ability

The mean scores of Oxford Shoulder Score and VAS decreased over time in both groups showing significant improvement ($p < 0.05$) (table 2).

There was not a significant interaction between time and group on Oxford Shoulder Score; $F(1.7, 84.2) = 1.07$, $p > 0.05$ and on VAS; $F(1.5,76.1) = 0.75$, $p > 0.05$, implying that the behavior of the two groups were similar during the study. Following up this interaction, contrasts indicated that there was no significant difference in the changes of VAS and functional ability over time between groups during each time interval of the treatment (from the baseline to the end of the treatment, from the end of the treatment sessions up to the follow up and from the baseline up to the follow up) $p > 0.05$ (table 3 and fig. 2a and b).

Table 1
Characteristics of patients with frozen shoulder before treatment in continuous US and sham US groups.

Parameter	Continuous US N = 20		Sham US N = 20		P value (t)
	mean	SD	mean	SD	
Age (years)	50.56	8.06	48.92	5.81	p > 0.05
BMI	22.04	2.52	23.16	2.96	p > 0.05
Duration (months)	5.24	1.96	5.48	1.87	p > 0.05
Sex male/female	10/15		10/15		(X^2) p > 0.05

SD: standard deviation, BMI: Body Mass Index.
p values are for baseline differences between the two groups. Significance level ≤ 0.05.
t: independent t -test, X^2: Chi Square test.

Range of motion

Range of motion in all directions improved significantly in both groups, $p < 0.001$ (table 2). There was no interaction between time and group on the range of motion for flexion, abduction, internal rotation and external rotation, $p > 0.05$, meaning that both groups improved in movement around shoulder by the same amount during each time period. Contrasts revealed no significant interaction all through the study (from baseline to the end of the treatment, from the end of the treatment sessions up to the follow up and from the baseline up to the follow up). There was only a significant interaction from the 10th session to follow up for abduction in a way that the sham Ultrasound group showed more improvement than the real Ultrasound group; $F(1, 48) = 4.94$, $p = 0.03$. However the changes were equal during the 10 treatment sessions and on the whole from baseline to the follow up (table 3 and fig. 3a, b, 3c, 3d).

Discussion

Currently, there is no agreement on the standard management of adhesive capsulitis, however physiotherapy has shown relatively positive effects in short and long term (Russell et al., 2014). Meanwhile the name physiotherapy encompasses a spectrum of different approaches and methods from mobilization to exercise alongside different physical modalities with no solid evidence behind their use.

To the best of our knowledge this study was the first to incorporate therapeutic US as the only physical modality alongside exercise and mobilization, and comparing it to the placebo US. Other studies have all included Ultrasound in combination to other thermal or electrical agents, making it impossible to reach to a solid conclusion regarding the exclusive effect of Ultrasound (Calis et al.,

Table 3
Interaction effects of Time and Group on shoulder pain (VAS), function (Oxford Shoulder Score) and Range of Motion (CI 95%).

Outcome measure time * Group interaction effects	DF	Error	F	P value
VAS	1.61	77.38	1.06	p > 0.05
Oxford Shoulder Score	2	96	0.76	p > 0.05
External rotation	1.55	74.56	1.54	P > 0.05
Internal rotation	1.22	58.67	1.14	P > 0.05
Abduction	2	96	2.56	P > 0.05
Forward flexion	2	96	0.137	P > 0.05

Significance level ≤ 0.05.

Table 2
Mean and SD of VAS, Oxford Shoulder Score and Range of Motion for continuous US and sham US groups at baseline, after treatment and at follow up (plus p values for baseline comparison).

Variable	Continuous US Mean (SD)			Sham US Mean (SD)		
	Before treatment	After treatment	follow up	Before treatment	After treatment	Follow up
VAS	76.88 (10.34) **p > 0.05**	23.40 (9.82)	12.52 (11.28)	72.36 (11.95)	23.20 (9.67)	12.00 (9.60)
Oxford Shoulder Score	51.20 (6.50) **p > 0.05**	22.08 (6.75)	15.28 (5.80)	51.12 (6.13)	25.00 (10.96)	16.36 (3.89)
External rotation	33.64 (10.41) **p > 0.05**	60.28 (12.39)	77.16 (16.69)	28.52 (10.89)	61.64 (8.56)	73.68 (11.58)
Internal rotation	17.84 (5.50) **p > 0.05**	32.68 (6.47)	51.84 (15.13)	17.44 (5.50)	34.20 (4.10)	48.44 (14.19)
Abduction	89.04 (9.16) **p > 0.05**	123.12 (14.43)	139.04 (21.22)	84.44 (8.75)	112.16 (11.10)	140.24 (18.74)
Forward flexion	133.04 (21.75) **p > 0.05**	151.68 (22.26)	163.44 (23.40)	133.64 (21.18)	155.24 (19.57)	163.92 (18.17)

*p values are for baseline differences between the two groups at significance level ≤ .05.

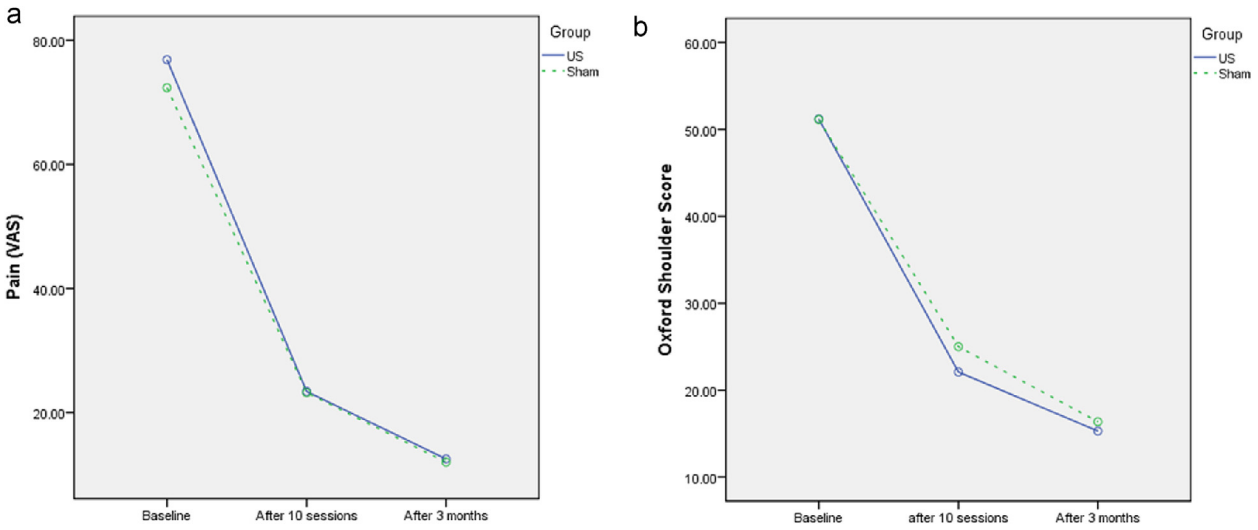

Fig. 2. Interaction graph for the effect of Time * Group on a. Pain, b. Function.

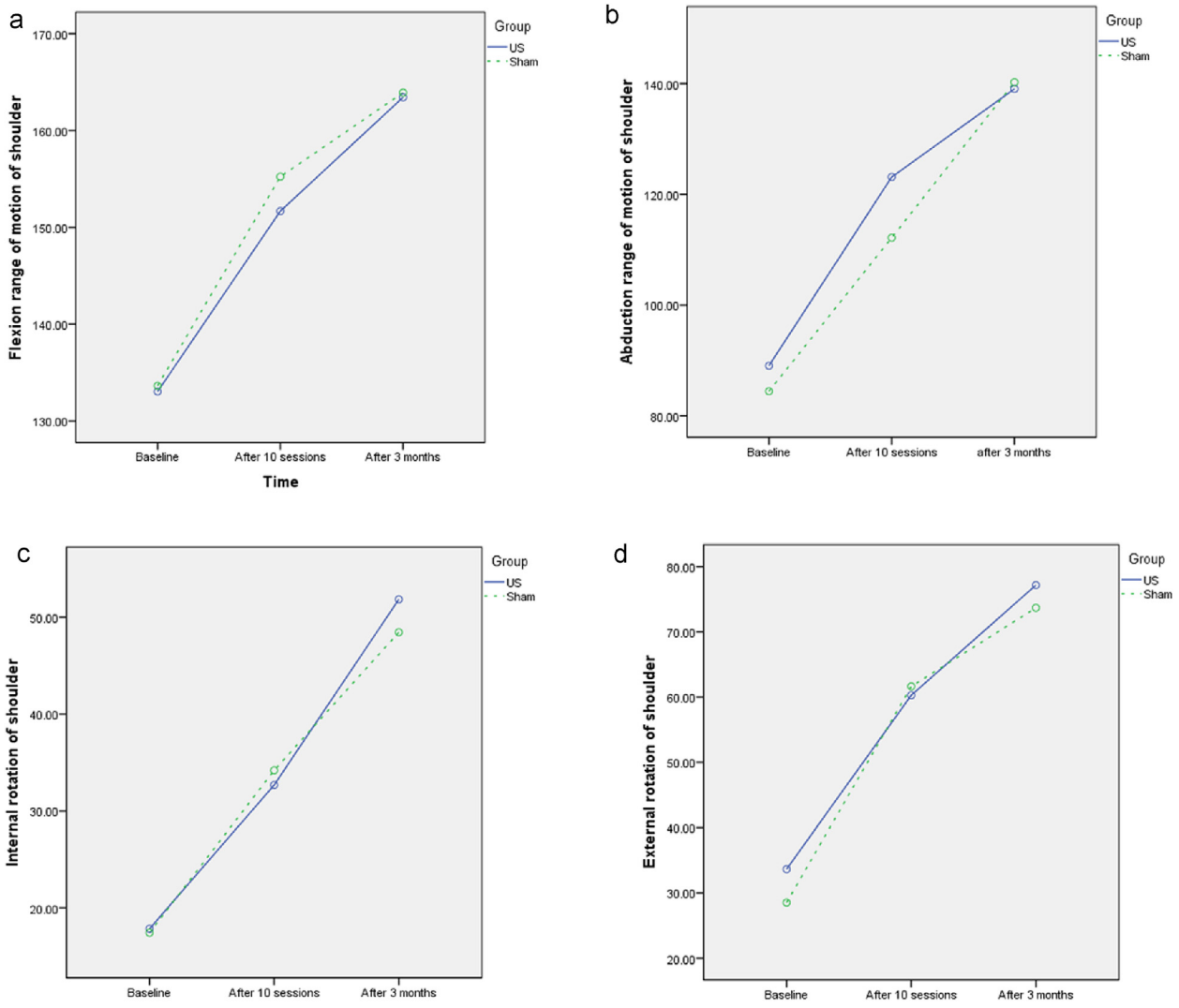

Fig. 3. Interaction graph for the effect of Time * Group on Range of Motion: a. flexion, b. abduction, c. internal rotation, d. external rotation (in degrees).

2006; Carette et al., 2003; Dogru et al., 2008; Page et al., 2014a; Page and Labbe, 2010).

In the current study, both groups improved significantly regarding VAS by a mean difference of 53.48 and 49.16 during the first 10 sessions of treatment and well along by a total mean of 64.36 and 60.36 up until the follow-up in the real Ultrasound and the sham Ultrasound groups respectively.

Also both groups improved functionally measured by Oxford Shoulder Scale with a mean difference of 29.12 and 26.12 during the treatment sessions and later by a total mean of 35.92 and 34.76 untill the follow up in Ultrasound and sham Ultrasound groups correspondingly.

In 2008 Dogru, published a study in which 49 patients with adhesive capsulitis were randomized to continuous Ultrasound and sham Ultrasound groups. Both groups also received hot pack and exercise for 2 weeks.Shoulder range of motion (goniometry), pain (VAS) and shoulder function (Shoulder Pain and Disability Index) were assessed before and after treatment and after 3 months follow up. Both groups improved significantly in all outcome measures; however the group receiving real Ultrasound showed greater changes regarding flexion, internal and external rotation after treatment. The results are partially in agreement with our findings given that we also witnessed significant improvement in pain, function and ROM in both groups during all measured time points.By the way the amount of improvement did not differ between groups in our study for all out come measures. This inconsistency may be due to some practical differences that exist between Dogru's study and the present study. Firstly, in their study, hot pack was added to ultrasound in both groups which as a superficial heating modality may interfere with the effects of deep heating modalities and is recommended not to be used together with the Ultrasound (Bélanger, 2015; Robertson and Low, 2006). Secondly, the ultrasound group had worse pre-treatment values and lower compliance with home exercises than participants in the placebo ultrasound group, which may have biased the results (Page et al., 2014a).

In another study Carrete et al. compared a combination of electrotherapy modalities TENS or Ultrasound with manual therapy or exercise (or both) to corticosteroid injection as an active intervention alone on 93 patients. Their results showed that the multicomponent intervention may be more effective than placebo injection at six weeks, but not at six or 12 months (Carette et al., 2003). The study had a high risk of performance and detection bias for the self-reported outcomes (Shoulder Pain and Disability Index (SPADI)) (Page et al., 2014a).Again Ultrasound was part of a package of treatment and was not compared to placebo.

Ansari in 2012 compared the effects of Ultrasound therapy plus end range mobilization to cryotherapy and stretching 6 days a week for 4 weeks, on pain, in 40 patients with primary adhesive capsulitis. They concluded that Ultrasound with end range mobilization produced better results than cryotherapy and stretching (Ansari SH et al., 2012). Again the results of their study are not comparable to the current study since Ultrasound was not compared to placebo. Additionally they had used different doses of therapy (pulse (ratio 1:4) ultrasound once a day for 24 days).

The equal improvement in pain and function as well as ROM in both groups in the current study can be attributed to the identical exercise regimen prescribed to both groups as well as equal joint mobilization maneuvers. Patients were regularly examined and checked by the therapist regarding the dosage and performance of the exercises. The rate of compliance to the exercise routine, measured by specific sheets with the name and dosage of each exercise, was high in both groups. Both groups seem to have benefited from exercise induced pain relief.

Home exercise programs instructed by a physiotherapist have shown significant benefits on patients' improvement already (Kivimaki et al., 2007; Russell et al., 2014). Exercise Induced Hypoalgesia has been characterized by elevations in pain thresholds and tolerances, as well as reductions in pain intensity ratings during and following exercise (Koltyn et al., 2014).

Although the exact mechanisms are unclear, the most widely considered mechanism is that the activation of the endogenous opioid system during exercise reduces pain perception following exercise. Exercise of sufficient intensity and duration is assumed to lead to the release of peripheral and central beta-endorphins, which are associated with changes in pain sensitivity (Ellingson et al., 2014; Naugle et al., 2012). Muscle contractions activate Group III (A-delta) and IV (C) primary afferents in the skeletal muscle, which in turn can activate the endogenous opioid system. Elevations in peripheral blood beta-endorphin concentrations have been reported in men following exercise, and it has been suggested that the stimulation of peripheral afferent neurons modulate pain by activating spinal or supraspinal inhibitory mechanisms (Naugle et al., 2012).

The obtained results from the current study are in accordance with the assumption that stretching exercises are a key component in managing musculoskeletal disorders (Leung and Cheing, 2008). The resulting increase in the range of motion due to stretch could have caused consequent improvement in the function. Furthermore, the equal improvement of both groups might as well be explained by the placebo effects of Ultrasound. Patients in both groups could have benefitted from the Placebo effects of the treatment. However the individual role of the placebo effects of the Ultrasound in the placebo group as well as the individual effect of mechanical movement of the Ultrasound head as well as the individual contributions of exercising and mobilization in both groups cannot be specified, although each one may have played a part in the outcome. A placebo effect of Ultrasound can be the result of moving the applicator head thus benefitting from the effects of massaging.Continuous movement of the applicator may increase the temperature of the area under treatment and may stimulate the skin receptors causing the pain gate control mechanism to become active. It has been shown that moving the applicator of US on the affected area can change the level of serum cortisol, which in turn can affect inflammation and swelling (Ebadi et al., 2012). Thus incorporating a third group without ultrasound in the future trials is suggested. Nevertheless, due to ethical considerations, it is not possible to have a real control group with no intervention to investigate the natural history of the disease.

Manual therapy including glenohumeral joint mobilization plus exercise is reported to provide patient reported treatment success and increase in active range of motion (Page et al., 2014b). In the present study we witnessed a significant increase in the flexion, abduction, external and internal rotation range of motion in both groups equally during the first 10 sessions of treatment and up until the follow up. It is difficult to discuss the additional increase in abduction from the end of the treatment sessions to the follow up in the sham Ultrasound group.It may be due to the individual differences in the tasks performed in everyday life by the patients in the sham group like chores that challenge overhead movements to a higher degree. The main contributor to the changes should be explored in a larger study.

The limitations to this pilot study need to be acknowledged. The sample size was relatively small which in turn hampers the generalizability of the results. Another source of weakness in this study would be that, even though obvious psychological problems were in the exclusion criteria, the state of the patients' anxiety level as well as stress and the amount of depression was not controlled for and these could have acted as intervening factors.

Future multicentral studies are needed to integrate different doses of Ultrasound into their design, such as different application

duration, frequency, mode and intensity, to explore the possible diverse effects that different dosages might have on the outcomes.

In the current study it would be assumable that the duration and intensity or even the number of sessions of Ultrasound application have not been sufficient to cause the proposed changes in soft tissue extensibility in response to Ultrasound application.

Despite the above mentioned limitations, this is the first time that real Ultrasound was compared to placebo Ultrasound and not in combination to other electrotherapeutic or thermal agents. It is imperative to find the most cost and time effective treatment approaches in different musculoskeletal problems and to provide reliable evidence on using different modalities to avoid irrelevant and useless health care interventions.

Further investigation and experimentation into the specific dose response relationship and the effect of ultrasound in different phases of adhesive capsulitis need to be performed in larger research designs and full scale studies.

Conclusion

This study was designed to prepare the ground for a better powered clinical trial on the possible contribution of Ultrasound therapy to treatment outcomes in adhesive capsulitis. The findings of this study suggest that continuous, 3 MHz, Ultrasound applied for 6 min around the shoulder capsule would not add to the benefits of a specific semi-supervised exercise regimen plus mobilization in patients suffering from primary adhesive capsulitis for more than 3 months.

Declaration of interest

The authors declare no conflicts of interest.

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