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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