ELSEVIER

Physiotherapy

Physiotherapy 102 (2016) 57–63

Evaluation of the effectiveness of three physiotherapeutic treatments for subacromial impingement syndrome: a randomised clinical trial

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Abstract

Objective To determine whether dexketoprofen administered by phonophoresis or iontophoresis is more effective for the treatment of subacromial impingement syndrome (SIS) than conventional ultrasound therapy.
Design Randomised clinical trial.
Setting University hospital.
Participants Ninety-nine participants with SIS without a complete tear of the rotator cuff were assigned at random to three intervention groups.
Intervention groups Participants received ultrasound ($n = 32$), phonophoresis with dexketoprofen (50 mg/session) ($n = 33$) or iontophoresis with dexketoprofen (50 mg/session) ($n = 34$). All participants completed 20 treatment sessions plus exercise therapy and cryotherapy.
Outcome measures A visual analogue scale (VAS), the Constant–Murley Scale (CMS) and the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire were administered pre-treatment (baseline), post-treatment and 1 month post-treatment.
Results At baseline, there were no differences between the groups. Post-treatment, VAS score improved by −1.2 points and CMS score improved by 8.9 points in the ultrasound group compared with the iontophoresis group [95% confidence interval (CI) −0.2 to −2.2 and 95% CI 17.0 to 0.7, respectively]. CMS score improved by 7.1 points in the phonophoresis group compared with the iontophoresis group (95% CI 14.8 to −0.7). At 1 month post-treatment, no significant differences were detected between the groups. VAS, CMS and DASH scores of all groups improved post-treatment and at 1 month post-treatment.
Conclusion Ultrasound, iontophoresis with dexketoprofen and phonophoresis with dexketoprofen can improve pain, shoulder function, and physical functioning and symptoms in the upper limb in patients with SIS without a complete tear of the rotator cuff.
Clinical Trials.gov registration number NCT01748188.

Keywords: Subacromial impingement syndrome; Ultrasound therapy; Phonophoresis; Iontophoresis; Dexketoprofen

Introduction

Subacromial impingement syndrome (SIS) is a common source of shoulder pain and dysfunction caused by an impingement of the rotator cuff tendon [1] between the head of the humerus and the acromion or the coracoacromial ligament as a result of changes in the subacromial space [2].

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http://dx.doi.org/10.1016/j.physio.2015.01.010

Patients with SIS are assessed by means of medical history and physical examination. The patients' symptoms, such as pain, limited mobility and decreased strength, may lead to a diagnosis of SIS. However, these assessments should be reinforced with tests for more accurate and precise diagnoses [3]. Diagnostic imaging techniques can assess the rotator cuff accurately and confirm the diagnosis [4]. Ultrasonography of the shoulder is a sensitive and specific method that requires standardised examination and expertise for optimal analysis [5].

The initial treatment of patients with SIS is conservative [1], and includes analgesics and non-steroidal anti-inflammatory drugs (NSAIDs), steroid injections and physiotherapy [6]. Physiotherapy aims to reduce inflammation in the tendons and strengthen the rotator cuff, eliminate pain and improve the patient's shoulder function [1]. It may include therapeutic exercise, mobilisation and manipulation, education and the application of physical agents such as ultrasound [7]. Ultrasound is among the most common treatments for SIS [8], but its effectiveness is debatable [6]. A recent study reported that ultrasound therapy is beneficial in the treatment of SIS, and is effective in decreasing pain and improving functionality [8]. Phonophoresis and iontophoresis combine the dual therapeutic action of physiotherapy and medication. In phonophoresis, a drug is used as a transmitter with ultrasound instead of the conventional conductor gel. Iontophoresis releases pharmaceuticals through the transcutaneous pathway using a low-intensity, low-voltage electric current. The three most common families of drugs used are anaesthetics, anti-irritation agents and anti-inflammatories [9]. Ketoprofen is an NSAID in the propionic acid class, with analgesic, anti-inflammatory and mild antipyretic effects. The analgesic effect is due to the S (+)-enantiomer (dexketoprofen) [10].

Pain control is an essential component of a successful physiotherapeutic programme to treat SIS [1]. Clinically, the pain and inflammation caused by SIS can be diminished through the use of techniques such as ultrasound, phonophoresis and iontophoresis [11]. Additionally, initial pain management typically involves NSAIDs [1]. Oral NSAIDs seem to be more effective than placebo in reducing pain in the first weeks after onset, and are therefore recommended in the acute phase [5]. To the authors' knowledge, no studies to date have described the use of the NSAID dexketoprofen with phonophoresis and iontophoresis in the treatment of SIS. Systematic reviews have highlighted the need for high-quality clinical trials that combine different techniques to reflect common practice [12–14]. As such, this study aimed to evaluate the combination of different techniques in the treatment of SIS. It was hypothesised that physiotherapeutic treatments favouring the penetration of an anti-inflammatory and analgesic drug would lead to an improved response to the treatment of SIS. The main aim of this study was to determine whether dexketoprofen administered by phonophoresis or iontophoresis is more effective for the treatment of SIS than conventional therapy with ultrasound.

Methods

A randomised, single-blind experimental clinical trial was developed, consisting of three treatment groups.

The sample size was determined using the GRANMO Version 7.11 sample calculator (March 2011), accepting an alpha risk of 5% (0.05) and beta risk of less than 20% (0.2) in a bilateral contrast. The power of the study was 80%. The calculations were based on detection of a difference of 12.2 points on the Constant–Murley Scale (CMS), assuming a standard deviation (SD) of 15.6 points and allowing for a 20% dropout rate. This generated a sample size of 33 subjects per group.

Setting and participants

The study population was comprised of 99 patients diagnosed with SIS without a complete tear of the rotator cuff. The patients were recruited from the Rehabilitation, Physiotherapy and Speech Therapy Service of Sant Joan University Hospital, Reus, Spain. Participants were selected based on inclusion and exclusion criteria (Table A, see online supplementary material).

Assessments were made pre-treatment (baseline), post-treatment and 1 month post-treatment. All visits were attended to by the same blinded rehabilitation doctor using standardised protocols.

The baseline assessment consisted of medical history, physical examination, a visual analogue scale (VAS), the CMS, the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire and various diagnostic tests (Yocum test, Jobe test, palm-up test and drop-arm test).

The diagnosis was confirmed by ultrasonography. All scans were performed by an expert radiologist in shoulder pathology, who diagnosed the pathology as tendinitis, tendinosis or partial tear. Tendinitis is characterised by the presence of inflammatory mediators, whereas tendinosis involves a disorganised collagen structure and changes consistent with hypoxia [7]. A partial tear involves less than 50% of the thickness of the tendon.

Fig. A (see online supplementary material) shows the selection and recruitment of the study population, and the distribution of participants in treatment.

Randomising and interventions

Each participant was assigned to one treatment group, at random, using a numbered list generated through the random permuted blocks method, applied by a statistician. The statistician was not involved in data collection or analysis. The three treatment groups were: ultrasound with no drugs (comparison group), phonophoresis and iontophoresis. The treatment sequence for all three groups was exercises + physical agent + cryotherapy. The three groups underwent standardised exercise therapy and cryotherapy in order to obtain the greatest benefits for the patients, as exercise has proven to be very effective for the treatment of SIS