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Research Protocol

There is Benefit to Strengthen the Rotator Cuff and Scapular Muscles in Patients with Lateral Elbow Tendinopathy? A Research Protocol

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Abstract

Background: Lateral elbow tendinopathy (LET) is one of the two most common tendinopathies of the upper limb. An exercise programme consisting of static stretching exercises, isometric and concentric-eccentric training has been recommended for the management of LET. Based mainly on clinical experience, rotator cuff and scapular musculature weakness in LET patients is commonly addressed increasing pain, decreasing functional ability and hand grip strength. The purpose of the present article will be to make a comparison of the effects of an exercise programme consisting of static stretching exercises, isometric and concentric-eccentric training and an exercise programme consisting of static stretching exercises, isometric, concentric-eccentric training and strengthening of rotator cuff and scapula muscles exercises for the treatment of LET.

Methods/Design: A randomized clinical trial (RCT) will be carried out with patients who have LET. They will be randomly allocated to two groups. Group A will be treated with static stretching exercises, isometric and concentric-eccentric training and group B will be treated static stretching exercises, isometric, concentric-eccentric training and strengthening of rotator cuff and scapula muscles exercises. All patients received five treatments per week for four weeks. Pain will be evaluated using a visual analogue scale and function using a visual analogue scale and pain-free grip strength at the end of treatment, at 3 months follow-up and at 6 months follow up. The change from baseline will be calculated for each follow-up. Differences between groups will be determined using the independent t test. The difference within groups between baseline and end of treatment will be analysed with a paired t test. A 5% level of probability will be adopted as the level for statistical significance. SPSS 21.00 statistical software will be used for the statistical analysis.

Discussion: The present trial is the first RCT to study the effectiveness of strengthening of rotator cuff and scapular muscles in LET management.

Trial registration: The study will submit in the Cyprus Ethics Committee.

Keywords: *Rotator Cuff; Scapular Muscles; Lateral Elbow Tendinopathy; Randomized Clinical Trial*

Background

Lateral elbow tendinopathy (LET) seems to be the most appropriate term to use in clinical practice because all the other terms such as lateral epicondylitis, lateral epicondylalgia, lateral epicondylosis and/or tennis elbow make reference to inappropriate aetiological,

anatomical and pathophysiological terms [1]. LET is one of the most common lesions of the arm work-related or sport-related pain disorder. The condition is usually defined as a syndrome of pain in the area of the lateral epicondyle [2] that may be degenerative or failed healing tendon response rather than inflammatory [3]. Hence, the increased presence of fibroblasts, vascular hyperplasia, proteoglycans and glycosaminoglycans together with disorganized and immature collagen may all take place in the absence of inflammatory cells [4]. The most commonly affected structure is the origin of the extensor carpi radialis brevis (ECRB) [4]. The dominant arm is commonly affected, the peak prevalence of LET is between 30 and 60 years of age [2,5] and the disorder appears to be of longer duration and severity in women [3,6].

The main complaints of patients with LET are pain and decreased function [2,3] both of which may affect daily activities. Diagnosis is simple, and a therapist should be able to reproduce this pain in at least one of three ways: (1) digital palpation on the facet of the lateral epicondyle, (2) resisted wrist extension and/or resisted middle-finger extension with the elbow in extension, and (3) by getting the patient to grip an object [2,3,5].

Although the signs and symptoms of LET are clear and its diagnosis is easy, to date, no ideal treatment has emerged. Many clinicians advocate a conservative approach as the treatment of choice for LET [2,3,7,8]. Physiotherapy is a conservative treatment that is usually recommended for LET patients [2-9]. A wide array of physiotherapy treatments have been recommended for the management of LET [10-14]. These treatments have different theoretical mechanisms of action, but all have the same aim, to reduce pain and improve function. Such a variety of treatment options suggests that the optimal treatment strategy is not known, and more research is needed to discover the most effective treatment in patients with LET [10-14].

One of the most common physiotherapy treatments for LET is an exercise programme [2-14]. One consisting of eccentric exercises has shown good clinical results in LET [15] as well as in conditions similar to LET in clinical behaviour and histopathological appearance, such as patellar and Achilles tendinopathy [16]. Such an exercise programme is used as the first treatment option for our patients with LET [9,17].

Eccentric training alone is not effective for many patients with tendinopathies [9]. Therefore, eccentric training is combined with static stretching exercises in the treatment of tendinopathies with positive results [15-20]. Furthermore, Malliaras and his colleagues concluded that clinicians should consider eccentric-concentric loading alongside or instead of eccentric loading in tendinopathy [16]. A pilot trial showed that an exercise program, consisting of isotonic strengthening, including eccentric, had reduced the pain in patients with rotator cuff tendinopathy at the end of the treatment and three months after the end of treatment [18]. Recently, isometric exercises are indicated to reduce and manage tendon pain [19-21]. LET is often related to forceful grip activities requiring isometric contraction of the wrist flexors and extensors [22]. Perhaps isometric contractions would be more beneficial than eccentric ones in lateral epicondylitis [22]. A case study showed that the combination of eccentric training with isometric contraction had positive effects in LET [20].

Based mainly on clinical experience, rotator cuff and scapular musculature weakness in LET patients is commonly addressed increasing pain, decreasing functional ability and hand grip strength [23]. To our knowledge, there have been no studies to investigate the effectiveness of rotator cuff and scapular muscle strengthening in the management of LET. It is possible to combine, static stretching exercises, isometric and concentric-eccentric training with strengthening of rotator cuff and scapula muscles exercises to see if the combination of the above reported therapeutic approaches offers superior results to isometric, and concentric-eccentric training alone in LET patients. Therefore, the aim of the present article will be to make a comparison of the effects of an exercise programme consisting of static stretching exercises, isometric and concentric-eccentric training and an exercise programme consisting of static stretching exercises, isometric, concentric-eccentric training and strengthening of rotator cuff and scapula muscles exercises for the treatment of LET.

Methods

A randomized controlled, monocentre trial will be conducted in the Cyprus Musculoskeletal and Sports Trauma Research Centre (CYMUSTREC) over 12 months to assess the effectiveness of an exercise programme consisting of static stretching exercises, isometric, concentric-eccentric training and strengthening of rotator cuff and scapula muscles exercises. A parallel group design will be used because crossover designs are limited in situations where patients are cured by the intervention and do not have the opportunity to receive the other treatments after crossover [24]. Three investigators will be involved in the study: (1) a physiotherapist, the primary investigator, (DS) who will evaluate the patients to confirm the LET diagnosis and will allocate patients to groups, (2) a physiotherapist (AC) who will perform all baseline and follow-up assessments, and will gain informed consent and (3) a physiotherapist, (AZC), who will administer the treatments. All assessments will be conducted by AC who will be blind to the patients' therapy group. AC will interview each patient to ascertain baseline demographic and clinical characteristics, including patient name, sex, age, duration of symptoms, previous treatment, occupation, affected arm and dominant arm.

A sample size of 25 subjects per group is sufficient to demonstrate statistical clinical significance for all outcome measures on lateral epicondylitis. Clinical effects of 20% had been reported as clinically meaningful in placebo-controlled studies measuring pain relief and functional outcomes in response to physiotherapeutic interventions such as low-power laser light. In this study, baseline variance for pain and functional outcomes will be set at 25%. Power calculations will suggest that a sample size of 25 patients per group is sufficient to detect a 20% change in outcome measures, assuming that variance will be equivalent to 25% with 80% of power and a 5% significant level. The formula that will be used to estimate the appropriate sample size will be:

$$N = 16\sigma^2/d^2$$

where σ^2 is the variability of the data and d^2 is the effect size. For example, in our trial $\sigma = 25$ and $d = 20$. Therefore the above formula is $N=16(25^2)/(20^2) = 16\chi625/400 = 25$

Patients over 18 years old who will been experiencing lateral elbow pain will been examined and evaluated in the CYMUSTREC) in Nicosia between April 2017 and February 2018. All patients will live in Cyprus, will be native speakers of Greek and will be either self-referred or referred by their physician or physiotherapist.

Patients will be included in the study if, at the time of presentation, they will have been evaluated as having clinically diagnosed LET for at least 4 weeks. Patients will be included in the trial if they report (a) pain on the facet of the lateral epicondyle when palpated, (b) less pain during resistance supination with the elbow in 90◦ of flexion rather than in full extension and (c) pain in at least two of the following four tests [7]:

1. Tomsen test (resisted wrist extension)
2. Resisted middle finger test
3. Mill's test (full passive flexion of the wrist)
4. Handgrip dynamometer test.

Patients will be excluded from the study if they have one or more of the following conditions: (a) dysfunction in the shoulder, neck (radiculopathy) and/or thoracic region; (b) local or generalized arthritis; (c) neurological deficit; (d) radial nerve entrapment; (e) limitations in arm functions; (f) the affected elbow had been operated on and (g) had received any conservative treatment for the management of LET in the 4 weeks before entering the study [24-28].

All patients will receive a written explanation of the trial prior to entry into the study. All patients will give signed informed consent to participate in the study. The study will be approved by the Cyprus Ethics Committee and access to patients will be authorised by the director (DS) of the CYMUSTREC.

The patients will be randomly allocated to two groups by drawing lots. Patients in Group A will be treated with static stretching exercises, isometric and concentric-eccentric training, and patients in Group B will be treated with static stretching exercises, isometric, concentric-eccentric training and strengthening of rotator cuff and scapula muscles exercises.

All patients will be instructed to use their arm during the course of the study but to avoid activities that will irritate the elbow such as grasping, lifting, knitting, handwriting, driving a car and using a screwdriver. They will also be told to refrain from taking anti-inflammatory drugs or other conservative treatment throughout the course of the study. Patient compliance with this request will be monitored using a treatment diary.

Communication and interaction (verbal and non-verbal) between the therapist and patient will be kept to a minimum, and behaviours sometimes used by therapists to facilitate positive treatment outcomes will be purposefully avoided. For example, patients will be given no indication of the potentially beneficial effects of the treatments or any feedback on their performance in the pre-application and post-application measurements [29].

In both groups the eccentric – concentric training combined with isometric contraction will be performed with the elbow on the bed in full extension, the forearm in pronation, the wrist in an extended position (as high as possible), and the hand hanging over the edge of the bed [20]. From this position, patients will flex their wrist slowly while counting to 30 [25,27,28], then will return to the starting position (extension) [20]. In the starting position, the patient will perform an isometric contraction of wrist extensors for 45 seconds [20]. When the isometric contraction will complete the patient will perform the eccentric – concentric contraction and so on [20].

In both groups three sets of 15 repetitions of slow progressive exercises of the wrist extensors at each treatment session will be performed, with 1-min rest interval between each set. Patients will be told to continue with the exercise even if they experience mild pain. However, they will be told to stop the exercise if the pain becomes disabling. The mild and disabling pain will be monitored asking the patient to rate the pain on VAS before and after treatment. Mild pain will be defined below 4 on VAS whereas disabling pain will be defined above 8 on VAS [25,27]. When patients are able to perform the exercises without experiencing any minor pain or discomfort, the load will be increased using free weights.

Static stretching exercises of the wrist extensors will be performed in all treatment groups. The static stretching exercises will be repeated six times at each treatment session, three times before and three times after the exercises, with a 30 second rest interval between each repetition. Static stretching exercises of the wrist extensors will be performed with the help of the other hand. The patient's elbow will be placed in full extension, the forearm in full pronation, and the wrist in flexion and ulnar deviation according to the patient's tolerance. This position will be hold for 30 - 45 seconds each time and then releases [25-28].

In group B the rotator cuff and scapular muscles will be strengthened. The strengthening exercises will include (i) shoulder medial and lateral rotation with the elbow in 0 and 90 degrees of abduction; (ii) shoulder abduction to 90 degrees with elbow in flexion: (iii) scaption-the arm was kept at 30 degrees of horizontal abduction with the thumb pointing downwards; and (iv) diagonal pattern from full flexion to extension [30]. Scapular muscle such as Rhomboids, upper trapezius, levator scapulae and serratus anterior will be strengthened in the present protocol [31]. Each exercise will be performed twice at each treatment session with 12 repetitions in each set and 1 min rest interval between each set. Patients will be told to continue with the exercise even if they experience mild pain. However, they will be told to stop the exercise if the pain becomes disabling (definition of mild and disabling pain please see above). When patients are able to perform the strengthening exercises without experiencing any minor pain or discomfort, the load will be increased using free weights or therabands.

Pain, function and drop-out rate will be measured in the present study. Structural changes in the tendon related to the treatment interventions will not be shown in the present study, because there is not an expert in this field. The last weakness will be covered in a future trial. Each patient will be evaluated at the baseline (week 0), at the end of treatment (week 4), at 3 month (week 16) and at 6 months (28weeks) after the end of treatment.

Pain will be measured on a visual analogue scale (VAS), where 0 (cm) will be "least pain imaginable" and 10 (cm) will be "worst pain imaginable". The pain VAS will be used to measure the patient's worst level of pain over the previous 24h before each evaluation, and this approach has been shown to be valid and sensitive of the VAS [32].

Function will be measured using a VAS, in which 0 (cm) will be taken as "no function" and 10 (cm) as "full function". Patients will be instructed to report their overall level of elbow function over the previous 24h before each evaluation, and this approach has been shown to be valid and sensitive of the VAS [32].

In addition, function will be measured by pain-free grip strength. Pain-free grip strength is defined as the amount of force each patient is able to generate with an isometric gripping action before eliciting pain [29]. Force will be measured in pounds with a Jamar hand dynamometer that had adjustable handles to accommodate different hand sizes. The arm will be placed in a standardised position of elbow extension, forearm pronation and internal rotation of the upper limb such that the palmar aspect of the hand faced posteriorly with the upper limb placed by the patient's side. Patients will be then instructed to squeeze the dynamometer handles until they will first experience pain and then to release their grip [29]. The attained grip force will be subsequently recorded, and the reading will not be visible to the patient. Three measures of pain-free grip strength will be recorded with a 30 seconds rest interval between each measurement, and the mean value of these repetitions will be calculated.

A drop-out rate will also be used as an indicator of treatment outcome. Reasons for patient drop out will be categorised as follows: (1) a withdraw without reason; (2) not returned for follow-up and (3) request for an alternative treatment.

The change from baseline will be calculated for each follow-up. Differences between groups will be determined using the independent t test. The difference within groups between baseline and end of treatment will be analysed with a paired t test. A 5% level of probability will be adopted as the level for statistical significance. SPSS 21.00 statistical software will be used for the statistical analysis.

Discussion

The main objective of this RCT is to determine the effectiveness of two physiotherapy protocols in improving pain, strength and function in patients with LET, at the end of treatment, at 3 months follow-up and at 6 months follow up. With the study conclusion, it is expected to test the following null hypothesis: "there is no difference in pain and function for participants undergoing physiotherapy intervention with or without strengthening of rotator cuff and scapular muscles". Despite its frequency and impact on athletic and non-athetic careers, and decades of research notwithstanding, management of LET remains frustrating and unpredictable for both athletes/non - athletes and clinicians. Systematic review [15] and RCT [33] favor eccentric over other types of contractions in the management of LET, but Martinez-Silvestrini., *et al*. (2005) [22] stated that, unlike Achilles tendinopathy, LET is often related to forceful grip activities requiring isometric contraction, which would be more beneficial than eccentric contraction in LET. Recently, isometric exercises have been recommended to reduce and manage tendon pain increasing the strength at the angle of contraction without producing inflammatory signs [34]. It has also been proposed that the positive effects of exercise programmes for tendon injuries may also be attributable to the effect of stretching. The aim of stretching is to lengthen the muscle-tendon unit, orientate the new collagen fibres and experience consequently less strain during joint motion [35]. Stretching may increase the range of motion of the relevant joint and strengthen the tendon or make it more resistant to strain [36,37]. Based mainly on clinical experience, rotator cuff and scapular musculature weakness in LET patients is commonly addressed increasing pain, decreasing functional ability and hand-grip strength [23]. This suggests that the underly-

ing causes of LET may not be restricted to the elbow region [23]. Functional impingement of the shoulder due to altered joint mechanism and muscle imbalance can impair the stabilization of the shoulder resulting in overcompensation of the extensors of the wrist [3]. This may lead to micro trauma of the soft tissue structures present at the lateral epicondyle thus causing symptoms of LET [3]. It is plausible that improvements with gripping might have occurred from a combination of improved motor control of the scapula and improved muscular strength of the scapular musculature [31]. Changes in the shoulder girdle may lead to altered and compensatory changes in the forearm and hand which may overload the muscles of the forearm during repetitive movements, thus causing symptoms of LET [3]. Using corrective scapular exercises and rotator cuff strengthening exercises, normal motion might have been restored, resulting in resolution of pain with activities and a return to pain-free gripping for the patient [31]. On the other hand, there are no studies to support this belief.

Conclusion

This is the first study to assess the strengthening of scapular and rotator cuff in the management of LET. It is expected, the study conclusion to contribute to the fund of scientific knowledge providing evidence that strengthening the rotator cuff and scapular muscles is a safe and effective tool in the management of LET symptoms, specifically pain and function.

Funding

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Availability of data and materials

Not applicable.

Authors' Contributions

DS conceived of the idea, developed the design of this trial, developed the intervention and wrote the article. AC recruited participants and are responsible for data acquisition. AZC provided advice on the study design and contributed to the content of the article. DL planned the statistical analysis. All authors read and approved the final manuscript.

Competing Interests

The authors declare that they have no competing interests.

Consent for Publication

Not applicable.

Ethics approval and consent to participate

The study will be approved by the Cyprus Ethics Committee. All patients will receive a written explanation of the trial prior to entry into the study. All patients will give signed informed consent to participate in the study. The patients will be free to abandon the study at any time without the obligation to give any explanation.

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