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Research Article

The Influence of Dexamethasone with Lidocaine Hydrochloride Iontophoresis in Recreational Tennis Players Suffering from Lateral Elbow Tendinopathy

Abstract

Background: Lateral elbow tendinopathy (LET) is a common clinical condition of the upper limb. Many treatments, medical and physical therapy, has been recommended for the management of LET. One of these recommended treatments is iontophoresis.

Objective: The aim of the present study was to determine the effects of iontophoresis using a combination of dexamethasone with lidocaine hydrochloride in the treatment of LET in recreational tennis players.

Methods: A Controlled clinical trial in the Physiotherapy Department of Panarkadikon hospital was conducted. Sixty eight patients who had LET for at least four weeks participated in the study. They were allocated to two groups by alternative allocation. Group A (n=35) received iontophoresis with dexamethasone and lidocaine hydrochloride and Group B (n=33) was treated with placebo iontophoresis. All patients received two treatments per week for six weeks. Pain, range of motion, pain free grip strength and function were evaluated at baseline, at the end of treatment and one month after the end of the treatment.

Results: A significant decrease in pain intensity in the iontophoresis group at the end of treatment and at one-month follow-up ($p < 0.01$, $p < 0.001$), compared with pretreatment values. Pretreatment values were also significantly lower than in the control group at the same time periods (< 0.01 , $p < 0.001$), pain free grip strength ($p < 0.05$ and $p < 0.01$, respectively) and function ($p < 0.05$ and $p < 0.05$ respectively) of the iontophoresis group increased significantly at the end of the treatment and at the follow up. Pretreatment values were also significantly lower than in the control group at the same time periods ($p < 0.05$, $p < 0.01$).

Conclusions: The solution of dexamethasone with lidocaine hydrochloride iontophoresis has positive effects in the treatment of LET in recreational tennis players. Further research is needed to confirm our results.

Introduction

Lateral elbow tendinopathy (LET), commonly referred to as lateral epicondylitis, lateral epicondylalgia, lateral epicondylitis and/or tennis elbow is one of the most common lesions of the arm. However, LET is the most appropriate term used in clinical practice because all the other synonyms refer to inappropriate aetiological, anatomical and pathophysiological terms [1]. The condition is usually defined as a syndrome of pain in the area of the lateral epicondyle [2-4], that may be degenerative or failed healing tendon response rather than inflammatory [5]. 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 [5]. The origin of the extensor carpi radialis brevis (ECRB) is the most commonly affected structure [5]. It is generally a work-related or sport-related pain disorder. The dominant arm is commonly affected, the peak prevalence of LET is

between 30 and 60 years of age [2,6] and the disorder appears to be of longer duration and severity in women [2,6,7].

The main complaints of patients with LET are pain and decreased function [2,8-12] 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 [1,8-10].

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 [2,8-11]. Physiotherapy is a conservative treatment that is usually recommended for LET patients [11,13,14]. A wide array of physiotherapy treatments have been recommended for the management of LET [11,15-17]. 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 [11,18-20].

Iontophoresis has attracted much interest in the last 20–25 years as it has been applied to common musculoskeletal conditions such as LET. It is a therapeutic technique that involves the introduction of ions into the body tissues by means of a direct electrical current [11]. Iontophoresis has several advantages as a treatment technique in that it is a painless, sterile, noninvasive technique for introducing ions into the tissue that has been demonstrated to have positive effect on the healing process [15]. Its effectiveness has been evaluated in a recently published systematic review [21] but conflicting results were revealed as to the effectiveness of iontophoresis for LET management. No known study has investigated in detail the effects of this therapy in recreational tennis players suffering from LET. Therefore, the purpose of this study was to determine the effects of a combination of dexamethasone with lidocaine hydrochloride for the treatment of LET in recreational tennis players.

Methods

A controlled, monocentre trial was conducted in the physiotherapy department of the Panarkadikon hospital over 27 months to assess the effectiveness of iontophoresis. A parallel group design was 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 [22]. Two investigators were involved in the study: (1) the director of orthopedic clinic of the Panarkadikon hospital who evaluated the patients to confirm the LET diagnosis (SD) and (2) a physiotherapist (AS) who performed all baseline and follow-up assessments, and gained informed consent. All assessments were conducted by AS who was blind to the patients' therapy group. AS interviewed 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.

Patients older than 18 years who were experiencing lateral elbow pain were examined and evaluated in the Panarkadikon hospital located in Tripoli between March 2011 and May 2013. All patients who lived in Arkadia, Greece, were either self-referred or referred by their physician or physiotherapist.

Patients were included in the study if, at the time of presentation; - had been evaluated as having clinically diagnosed LET for at least 4 weeks and were recreational tennis players; reported (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 [1]:

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 were excluded from the study if they had 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 [2,23,24].

All patients received a written explanation of the trial prior to entry into the study. All patients gave signed informed consent to participate in the study. The study was approved by the Panarkadikon Hospital ethics committee.

The patients were allocated to two groups by sequential allocation. For example, the first patient with LET was assigned to the iontophoresis group (IG), the second patient with LET to the placebo iontophoresis group (PIG), and so on.

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

Communication and interaction (verbal and non-verbal) between the therapist and patient was kept to a minimum, and behaviours sometimes used by therapists to facilitate positive treatment outcomes were purposefully avoided. For example, patients were 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 [25].

The Phoresor II (IOMENT, Inc., Salt Lake City, Utah) was used in the present study. The subject in the IG was sat in a relaxed position with the elbow to rest in the bed. Then the target treatment area was thoroughly cleansed with methyl alcohol and allowed to dry. Following the skin preparation, a bipod electrode system with a positive and a negative electrode was properly secured against the skin. The active electrode was placed directly over the site of application of the lateral epicondyle and the negative electrode was placed on an adjacent location. The distance between active and dispersive electrode was approximately 15 cm. The treatment drug was 1 cm³ of dexamethasone (4 mg/ml sodium phosphate) and 2 cm³ of lidocaine hydrochloride (4% lidocaine hydrochloride) that were drawn separately into a 3 cm³ syringe. This solution was introduced into the positive electrode via the entry portal with a conventional needle and syringe. The current control DC generator was turned to 2 Milliampere (mA) for 5' (prime minutes). It was increased progressively to 3 (mA) and held there for the next 5', and then increased to 4 (mA) for the remaining 10', giving a total treatment time of 20'. Post-treatment massage cream was rubbed on to the skin over both electrode sites to assist in reduction of any minor skin irradiation that sometimes occurs as a result of the treatment. Patients received 12 treatments (2 times per week over 6 weeks).

The same procedure was followed for the PIG, except that the drug was different. All subjects received a 2 ml sodium chloride

solution. Both dexamethasone and sodium chloride solutions were clear, colorless and odorless, therefore neither the patient nor the therapist were able to distinguish between the two forms of treatment due to the appearance of the solutions.

Pain, range of motion (ROM), pain-free grip strength and function were measured in the present study. Each patient was evaluated at the baseline (week 0), at the end of treatment (week 6) and at 1 month (week 10) after the end of treatment.

Pain was measured on a visual analogue scale (VAS), where 0 (cm) was “least pain imaginable” and 10 (cm) was “worst pain imaginable”. The pain VAS was used to measure the patient’s worst level of pain over the previous 24 h before each evaluation, and this approach has been shown to be valid and sensitive of the VAS [26]. ROM was measured with a plastic, large, clear, 360° goniometer. The subject, with elbow extended and forearm pronated, flexed the wrist and, at the point that pain was felt, recorded the degree of motion. 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 [25]. Force was measured in pounds with a Jamar hand dynamometer that had adjustable handles to accommodate different hand sizes. The arm was placed in a standardized 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 were then instructed to squeeze the dynamometer handles until they first experienced pain and then to release their grip [39]. The attained grip force was subsequently recorded, and the reading was not visible to the patient. Three measures of pain-free grip strength were recorded with a 30-s rest interval between each measurement, and the mean value of these repetitions was calculated.

Function was measured using free weights. The recreational tennis players’ forearm supported on a table with the shoulder in sixty degrees of flexion, elbow was fully extended and forearm pronated. From this position the subject lift the hand in wrist extension, without pain, weights of 1, 2 and 3 kg.

A mixed 2x3 repeated measures ANOVA model was used to analyze the data from each variable within groups (IG, PIG) among treatment phases and follow up period and between groups (IG Vs PIG) at baseline, end of treatment and one month follow up. Multiple comparisons by Bonferroni post-hoc method and independent-samples-t-tests were used to highlight the significant differences where needed. The probability level for significance was set at 0.05 [27]. All parameters are shown as mean ± SD. The SPSS (version 19.0 for Windows 2008) statistical package we used to analyze the data.

Results

Ninety five patients eligible for inclusion visited the hospital within the trial period. Seven were unwilling to participate in the study, and three did not meet the inclusion criteria described above. The other 85 patients were sequentially allocated to one of the two possible groups: (a) group IG (n = 43)45.2±2.86 years old men, (b) group PIG (n = 42); 45.7±2.72 years old men (Table 1). There were 8 dropouts from the IG and 9 from the PIG. 6 recreational tennis players of the IG group and 5 from the PIG dropped out, because had

too much pain and they wanted to withdraw from the study to take medication. In addition, 2 more men from the IG and 4 from PIG did not complete the study protocol due to other personal problems. Patient flow through the trial was summarized in a CONSORT flow chart (Figure 1).

The mean age of the patients was about 45 years, and the duration of LET was about 6.2 months. LET was in the dominant arm in 89% of patients. There were no significant differences in mean age (P > 0.05, independent t - test) or the mean duration of symptoms (P > 0.05, independent t - test) between the groups.

VAS of the IG decreased, at the end of the treatment (p<0.01) and at the end of the one month follow up (p<0.001), compared with baseline values (Table 2). VAS of the PIG did not change significantly at the treatment or at the end of the follow up period, so that at the

Table 1: Descriptive characteristics of the recreational tennis players.

	IG (n=35)	PIG (n=33)
Age (yrs)	45.2±2.86	45.7±2.72
Height (cm)	172.0±1.02	175.0±1.04
Weight (Kg)	75.4±2.24	75.9±2.14
Duration of symptoms (months)	6.28±2.7	6.20±2.8

IG = iontophoresis group; PIG = placebo iontophoresis group; Mean (SD)

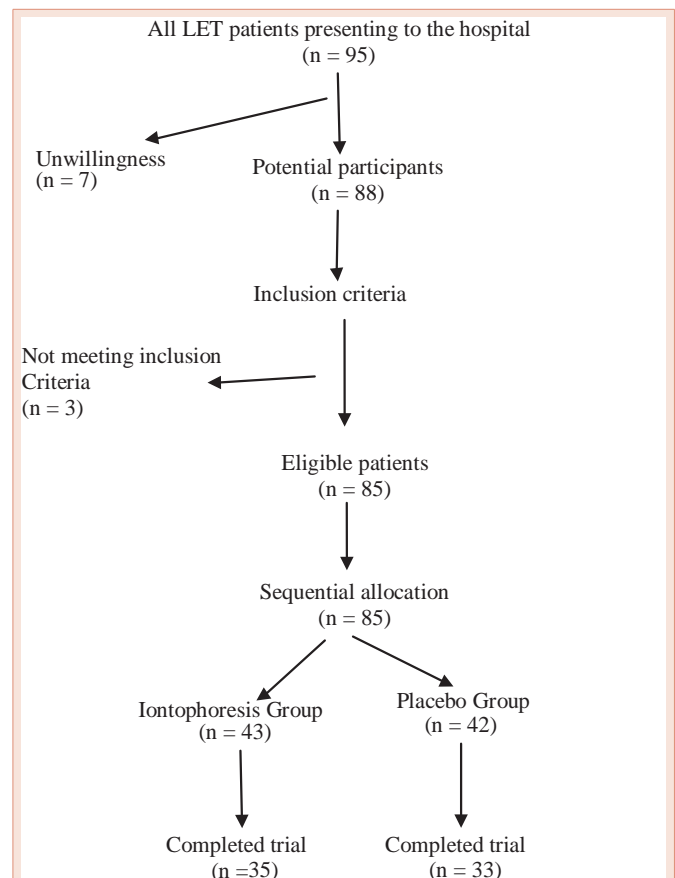


Figure 1: Flow chart of the study.



end of the treatment and at one month follow-up was significantly higher ($p < 0.01$ and $p < 0.001$ respectively) than the IG (Table 2).

The mean flexion of the wrist of the IG increased significantly at the end of the treatment and at the end of the follow-up ($p < 0.05$), compared with pre-treatment values (Table 2).

The mean pain-free grip strength of the IG increased, at the end of the treatment ($p < 0.05$) and at the end of the one month follow-up ($p < 0.01$), compared with baseline values (Table 2). The mean pain-free grip strength of the PIG did not change significantly at the end of the treatment or at the end of the follow up period, so that at the end of 12 treatments and at the end of the follow up was significantly lower ($p < 0.05$ and $p < 0.01$ respectively) than the IG (Table 2).

The mean free weights of the IG increased, at the end of 12 treatments ($p < 0.05$) and at the end of the one month follow-up ($p < 0.05$) compared with baseline values (Table 2). The mean free weights of the PIG did not change significantly at the end of the treatment or at the end of the follow-up period, so that at the end of 12 treatments and at one month follow-up was significantly lower ($p < 0.05$ and $p < 0.001$) than the IG (Table 2).

During the treatment process no complications were reported.

Discussion

The results obtained from this controlled clinical trial are novel; as to date, there have been no data comparing the effectiveness of iontophoresis using dexamethasone and lidocaine hydrochloride versus placebo iontophoresis in recreational tennis players suffering from LET. Iontophoresis produced the largest effect (decrease of pain, increase of function, ROM and pain free grip strength) at the end of the treatment (week 6) and 1 month (week 10) after the end of the treatment.

Iontophoresis has attracted much interest as it is applied to common musculoskeletal conditions such as LET. It uses continuous direct current of low amperage to introduce topically applied physiologically active ions through the body surface with the advantages of including its noninvasive nature, uniform absorption and absence of systemic side effects such as gastrointestinal distress [28].

LET is an overuse syndrome that is characterized by degeneration.

The area of the extensor wrist muscles insertion is very weak; the collagen fiber is not in alignment because of failure healing resulting in irritation of free nerve endings and pain production. This pain does not allow the recreational athlete to use the elbow in particular motions. It is supported that dexamethasone iontophoresis can replace local steroid injections, decrease local pain, realign the collagen fibers near to insertions in the periosteum and restore the function of the wrist extensor muscles [29]. Moreover, the difference between other traditional physical therapy methods and iontophoresis is that it can reduce pain in a faster way and permits the patient to be functional [30]. Iontophoresis has many advantages in comparison with local injections without side-effects. These advantages may be classified as follows [31,32]: a) permits consistent drug delivery; b) a low systematic dose is administered; c) the sterile barrier of the skin is not compromised, which is of particular importance when corticosteroid drugs are used; d) the treatment is painless. Pain due to needle insertion and tissue tension caused by the subcutaneous injection of a fluid volume is not produced and e) the treatment is a traumatic. Tissue damage due to needle penetration and the subcutaneous injection of a bolus of fluid is avoided.

The results of the present study are in line with the results of the study by Harris [33], in which 26 patients with lateral epicondylitis received iontophoresis and it was observed that 75% of the patients had an improvement in symptoms, 14% had significant relief of pain and 11% had slight or no relief of pain. However, Harris [33] used dexamethasone with xylocaine, whereas in the present study was used a solution of lidocaine hydrochloride and many more subjects were treated for a prolonged period of time. Tamburini and Di Monte [34] showed that iontophoresis improved the symptoms and the recovery time in football players who suffered from overuse syndromes such as tendonitis and tendonosynovitis, but their study had methodological problems (neither blinded, nor placebo). Conversely, in another study, Bertolucci [35], investigated the effects of dexametason iontophoresis in bicipital tendonitis, sacroiliitis, supraspinitis, infraspinitis, adhesive capsulitis of the shoulder, peroneal tendonitis, pes anserinus bursitis / tendonitis and LET. It was found that the patients had no significant pain relief using dexametason iontophoresis.

A recently systematic review found conflicting results on iontophoresis effectiveness in the management of LET [21], it cannot

Table 2: Pain, range of motion, pain free-grip strength and function of iontophoresis group and placebo iontophoresis group at baseline, at the end of treatment (week 6) and at one month follow-up (week 10) (mean \pm SD).

Variables	Group	WEEK 0	WEEK 6	WEEK 10
Pain (mm)	IG	88.96 \pm 4.27	49.65 \pm 2.42**	17.24 \pm 1.33***
	PIG	91.68 \pm 3.68	78.91 \pm 3.06**	71.85 \pm 2.65***
Range of Motion (Degrees)	IG	78.1 \pm 5.51	82.8 \pm 6.12	86.1 \pm 6.34*
	PIG	77.3 \pm 5.72	78.5 \pm 5.85	77.9 \pm 5.67
Pain free-grip strength (Kg)	IG	24.81 \pm 2.29	31.63 \pm 3.17*	39.72 \pm 3.88**
	PIG	25.98 \pm 2.23	26.15 \pm 2.31*	25.83 \pm 2.34**
Function - Free weights (Kg)	IG	1.13 \pm 0.18	1.22 \pm 0.23*	1.33 \pm 0.28*
	PIG	1.11 \pm 0.16	1.13 \pm 0.17*	1.15 \pm 0.19**

Significant differences from BASELINE values: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Significant differences between groups (IG vs PG): * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$



be ruled out from research, as it is a dose-response modality and the optimal treatment dose has obviously not yet been discovered. A dose-response analysis are needed to be carried out but it is difficult to test for a dose response, because of poor reporting of variables and a dearth of clinical studies comparing the effectiveness of different treatment modality variables. Factors that are the key to an effective iontophoresis treatment are the accuracy of diagnosis, the age of the patient and the duration of the condition (acute versus chronic) being treated [36].

However, this trial does have some shortcomings. First, a power analysis was not performed. Second, although this study was not a randomized controlled trial because a genuine randomization procedure was not followed, the use of sequential allocation to allocate patients to treatment groups allowed a true cause and effect relation to be demonstrated. Third, the patients in the placebo iontophoresis were without treatment for a long period of time. There was the intention to treat the placebo group subjects with traditional physiotherapy modalities plus iontophoresis if they wanted, until their problems were solved. Finally, the blinding of patients and therapists would be problematic in that case, if not impossible, because patients know if they are receiving the iontophoresis treatment and therapists need to be aware of the treatment to administer it appropriately. In addition to these weaknesses, structural changes in the tendons related to the treatment intervention were not shown, and the long-term effects (6 months or more after the end of treatment) of iontophoresis were not investigated. Further research is needed to establish the possible mechanism of action of this treatment approach, and the cost-effectiveness of such treatment, because reduced cost is an important issue for the recommendation of any given treatment.

Conclusions

The results of this study, suggests that iontophoresis using a solution of dexamethasone with lidocaine hydrochloride is effective in the treatment of recreational tennis players suffering from LET in terms of reducing pain and improving function. Future well – conducted RCTs are needed to confirm the results of the present trial.

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