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Effectiveness of Iontophoresis for Lateral Elbow Tendinopathy

Stasinopoulos Dimitrios*, Papadopoulos Konstantinos and Konstantinou Antonis

Department of Health Sciences, School of Sciences European University of Cyprus 6, Diogenes Str. Engomi, P.O.Box 22006, 1516, Nicosia, Cyprus

Abstract

Objective: The aim of the present review was to determine the effectiveness of iontophoresis in the management of lateral elbow tendinopathy (LET) and to provide recommendations based on this evidence.

Background data: LET is a common clinical condition, and a wide array of physiotherapy treatments is used for treating LET.

Methods: Randomized controlled trials (RCTs) identified by a search strategy in six databases were used in combination with reference checking. RCTs that included iontophoresis, patients with LET, and at least one of the clinically relevant outcome measures were selected. Aqualitative analysis of the selected studies was conducted using the Chalmers' technique.

Results: Four RCTs fulfilled the criteria and were included in the review. Although these studies had satisfactory methodology, shortcomings were not absent; conflicting results were revealed as to the effectiveness of iontophoresis for LET management.

Conclusions: Iontophoresis need not be ruled out for LET as it is a dose-response modality, and the optimal treatment dose has obviously not yet have been discovered. Further research with well-designed RCTs is needed to establish the absolute and relative effectiveness of this intervention for LET.

Keywords: Iontophoresis; Tennis elbow; Epicondylitis, Ion transfer; Lateral elbow tendinopathy

Introduction

Lateral elbow tendinopathy (LET), commonly referred to as lateral epicondylitis, lateral epicondylalgia, lateral epicondylosis and/or tennis elbow is one of the most common lesions of the arm. However, LET is the most appropriate term to use in clinical practice because all the other terms make reference to inappropriate a etiological, 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. Iontophoresis 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 than 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 two previously published systematic reviews, which have addressed the effectiveness of conservative treatments for LET [21,22] but conclusions, positive or negative, cannot be drawn from these two reviews because of the small number of studies included. To our knowledge, there has been no review of iontophoresis for LET. Therefore, the aim of the present article was to determine the effectiveness of iontophoresis in the management of LET and to provide recommendations based on this evidence.

***Corresponding author:** Stasinopoulos Dimitrios, Department of Health Sciences, School of Sciences European University of Cyprus, Diogenes Str. Engomi, P.O.Box 22006, 1516, Nicosia, Cyprus; E-mail: D.Stassinopoulos@euc.ac.cy

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Methods

Search strategy

Computerized searches were performed using Medline (from 1966 to December 2012), Embase (from 1988 to December 2012), Cinahl (from 1982 to December 2012), Index to Chiropractic literature (from 1992 to December 2012), Chirolars (from 1994 to December 2012), and Sports Discus (from 1990 to December 2012) databases. Only English language publications were considered. The following search terms were used individually or in various combinations after studying the relative literature and discussing with experts in the relevant area: "tennis elbow," "lateral epicondylitis," "lateral epicondylalgia," "LET," "lateral epicondylosis," "rehabilitation," "iontophoresis," "ion trasnfer," "medication," "drugs," "clinical trials" and "randomised control trials." Other references were identified from existing reviews, and other papers cited in the publications were searched. Further citations from the reference sections of papers retrieved, were sought by contacting experts in the field. Others were obtained from the Cochrane Collaboration (last search December 2012), an international network of experts who search journals for relevant citations. Unpublished reports and abstracts were not considered. Keywords and search strategy were selected by one researcher only (AK), without the help of an expert librarian with experience in searching databases to computerized health literature.

Selection of studies

To be included within the review, a study had to meet the following conditions: it had to be a randomized control trial (RCT) with or without follow-up, which included subjects aged >18 years old treated for LET. Patients suffered from LET for at least one month (4 weeks). The treatment had to be any type of iontophoresis evaluated against at least one of the following: (i) placebo; (ii) no treatment; (iii) another treatment, conservative (physical therapy intervention or medical) or operative. RCTs in which iontophoresis was given as part of the treatment—for example, iontophoresis and LLLT or ultrasound and exercise program and iontophoresis-were excluded, because we would not know how each modality contributedto the results. However, the effectiveness of thesemanagement strategies has not been assessed in the literature. Data were sought for one of the following four primary outcome measures: pain (scales or description words), function (scales, tests, or description words), grip strength (pain-free or maximum), and a global measure (overall improvement, proportions of patients recovered, subjective improvement of symptoms).

The titles and abstracts of all studies were assessed for the above eligibility criteria. If it was absolutely clear from information provided in the title and/or abstract that the study was not relevant, it was excluded. If it was unclear from the available abstract and/or the title, the full text article was retrieved. There was no blinding to study author, place of publication, or results. The researchers assessed the content of all full text articles, making the selection criteria.

Methodological quality

The quality of the selected papers was examined using the system proposed by Chalmers et al. [21] with some minor modifications, which evaluates the design and conduct of the research by scoring the analysis. The quality of the selected papers were scored by two researchers (DS and KP). According to Labelle et al. [18] it is possible to interpret the results appropriately using this system, especially when there are conflicting results between two studies, or studies with small sample sizes and inconclusive results.

The Chalmers' technique consists of two evaluation forms, with individually scored items, allowing a maximum score of 100. The first form examines the study design, giving particular importance to blinding of patients and doctors, and the presence and method of randomization of the patients and doctors when applicable (Table 1). The second form evaluates the quality of the data analysis, the statistical analysis, and the presentation of results (Table 2).

This system was applied to several hundred therapeutic trials, and an arbitrary score of 70% was considered to be the minimum required for a high quality design for controlled therapeutic trials. If the score was below 40% (0-39%), the design of the study was considered low quality, and if it was 40-69%, it was satisfactory [18].

Data abstraction

Raw data on means for all outcomes, as well as the authors' report of the study results, were extracted from the full manuscripts by one researcher (AK). Data on adverse events were abstractedfrom the studies.

Basic data were extracted including characteristics of participants (e.g., age, gender, previous treatments, and duration of disorder), outcomes (type of outcome measure and instrument) and interventions (type, dose or intensity, frequency, and duration).

Items	Possible points
Description of selection of subject was adequate	0-3
Description of patients screened was provided	0-3
Inclusion criteria for study included	0-2
Exclusion criteria for study included	0-2
Withdrawals and reason for withdrawal were described	0-3
Therapeutic regimen definition	0-3
Control appearance	0-2
Randomisation was blinded	0-10
Patients were blinded to treatment group	0-8
Investigators were blinded to treatment group	0-8
Power calculations (sample size requirements)	0-4
Adequacy of randomisation was evaluated	0-4
Adequacy of blinding was evaluated	0-3
Compliance with treatment was assessed	0-3
Measure of outcome of active therapy was made	0-2
The total possible score is 60.	

Table 1: Evaluation form A, adapted from Chalmers et al. [21] showing the 15 items scored to evaluate the study design of a clinical trial.

Items	Possible points
Dates of study description	0-2
Results of randomisation	0-2
Post type 2 estimate	0-3
Confidence limits	0-3
Time series analysis	0-2
Timing of evens	0-4
Correlation	0-2
Statistical analysis	0-4
p Value	0-2
Withdrawals	0-4
Handling withdrawals	0-4
Side effects	0-2
Retrospective evaluation	0-3
Presentation of results	0-3
The total possible score is 40.	

Table 2: Evaluation form B adapted from Chalmers et al. [21] showing the 14 items scored to evaluate the data analysis of a clinical trial.

Authors	n	Method of treatment	Outcome measures	Conclusions	Quality scores
Demirtas and Oner (1998)	40 (20M, 20F)	Iontophoresis sodium salicylate vs iontophoresis sodium diclofenac	Pain	Iontophoresis of diclofenac is more effective than iontophoresis of sodium salicylate	38
Runeson and Haker (2002)	64 (41M, 23F)	Iontophoresis with corticosteroids vs placebo iontophoresis	Pain Grip strength	No difference at the end of treatment or at the follow ups	75
Tascioglu, Oner and Armagan (2003)	60 (23M, 37F)	Ibuprofen iontophoresisvs low energy laser	Pain Grip strength function	Ibuprofen iontophoresis is better than low energy laser	47
Stefanou, Marshall, Holdan and Siddiqui (2012)	82 (44M, 38F)	Iontophoresis via dexamethasone using a self contained patch with a 24-hour battery vs 10 mg dexamethasone injection vs 10 mg triamcinolone injection	Pain Grip strength function	Dexamethasone via iontophoresis produced short–term benefits	77

Table 3: Results for four studies on treatment by iontophoresis.

Results

Trial flow

Using the criteria established for inclusion, 8 studies were included. After review of the completed texts, four studies were excluded [23-27] leaving four eligible RCT's to be included in the review [28-31]. No additional eligible RCTs were found by screening the references.

Description of studies

Three studies [29-31] explicitly excluded patients with concomitant neck, thorax, or shoulder complaints, and one study [28] excluded patients with skin disease.

Two studies [29,31] performed a long-term follow up (6 months or more after the end of treatment). The other two studies [28,30] did not perform long term or short term follow up.

In all studies, the study population consisted of subjects of both sexes over a wide range of ages suffering from chronic LET (at least 4 weeks after the onset).

Pain was the primary outcome measure for all studies. Pain was measured either by visual analogue scales (VAS) [29,31], four points scale [28,30], or pain provocation tests [28-30]. Function had also been measured in both studies either by patient-rated tennis elbow evaluation [29], work status [29] or tests such as the lifting test [28]. Other outcome measure was the grip strength. Grip strength was reported in 3 studies [27-29], Grip strength was measured either as pain free grip strength [28] or maximum grip strength [27]. One study [29] did not specify the way that grip strength was measured.

One study gave enough details in relation to the blinding of patients [27]. Two studies blinded the therapists [27,29]. In two studies, outcome assessors were reported to be blinded to the intervention [27,28].

Two studies described the method of randomization [27,29] in detailed whereas the rest did not clearly describe the randomization process.

All studies reported drop-outs and the reason for drop-outs. Side effects were also reported in all studies.

The sample size of the studies ranged between 20 [26] and 41 [29] patients per intervention group. No one study stated the power calculations for the sample size.

Effectiveness

Table 3 shows our evaluation for the 4 clinical trials, expressing the results as percentages of the maximum possible score and allowing for items which were not applicable to every study and which therefore excluded from the calculations. The average score for the four trials was 59.25%, with a minimum of 38% for the weakest study design [27] and a maximum of 77% for the strongest one [29].

One out of four studies compared the effects of iontophoresis with placebo [27], two studies compared iontophoresis with other treatment approach such as low energy laser [28] or injection [29] and one study compared two different types of iontophoresis [26].Two out of these four studies had high quality design [27,29]. Iontophoresis was more effective than other treatment approaches in the management of LET [28,29] at the end of treatment but just one of these two studies showed short term positive effects of iontophoresis [29]. One study [27] showed that iontophoresis was not a better treatment approach than placebo iontophoresis in long term.

Discussion

In this review, the effectiveness of iontophoresis was assessed by searching databases in combination with reference checking for randomized controlled clinical trials. It is the first to include a satisfactory number of studies that assessed the effectiveness of iontophoresis in the management of LET. Conflicting results were found.

Iontophoresis has attracted much interest as it is applied to common musculoskeletal conditions such as LET. Iontophoresis uses continuous direct current of low amperage to introduce topically applied physiologically active ions through the body surface. Advantages of iontophoresis include its noninvasive nature, uniform absorption and absence of systemic side effects such as gastrointestinal distress [31]. Although this review found conflicting results on iontophoresis effectiveness in the management of LET, it cannot be ruled out from research, as it is a dose-response modality and the optimal treatment dose has obviously not yet been discovered. It was our intention to carry this out as a dose-response analysis. However, it was 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.

The findings of our review are in accordance with the previously published systematic reviews by Bisset et al. [20] and Trudel et al. [11] which evaluated the effectiveness of physiotherapy and conservative treatments in the management of LET, respectivelyMoreover, a systematic review of no dose response parameters was carried out in the above both reviews, as we did in our review.

Although overall the quality of studies included in the review was satisfactory, there were methodological limitations. Many of the studies failed to provide adequate long term follow up, blinding, and power calculations. The use of standardized outcome measures was another area of particular deficitsince studies used many and

different outcome measures for pain, function and strength. Finally, the protocol of the intervention was not described in full detail, making replication difficult. Therefore well designed RCTs are needed to investigate the effectiveness of iontophoresis in the management of LET.

Methodological shortcomings of this systematic review include searching in English alone, lack of trials selection blinding, and absence of meta-analyses. However, information on the selection criteria is often missing from the methods section of an article, so blinding has to be broken to retrieve it, as there is evidence that a difference may exist between blinded and unblended reviews. This is very time consuming, and the differences show little consistency in direction of bias or its magnitude [30]. For these reasons, we decided that the reviewers should not beblinded to the above characteristics, even though this may haveincreased the possibility of methodological quality and dataanalysis bias. Moreover, it may sometimes be difficult for reviewersto decide whether it is clinically relevant to combinethe results of a group of studies in a meta-analysis-for example, studies of patients with different types of treatment, differenttypes of comparison groups, or different clinical characteristicsof patients studied. There is consensus among the editorial boardof the Cochrane Back Review Group that, if relevant valid dataare lacking (data are too sparse or of too low quality) or if dataare statistically and clinically too heterogeneous, a meta-analysisshould be avoided and reviewers should perform a qualitative review [31]. For these reasons, a qualitative review was conducted.

Conclusion

This review found conflicting results for the effectiveness of iontophoresisin LET. Based on this evidence, it is impossible to recommend iontophoresis as a treatment approach in the management of LET. However, iontophoresis cannot be ruled out, as it is a dose-response modality, and the optimal treatment dose has obviously not yet have been discovered. In addition, the included studies had methodological shortcomings. Therefore, further research with well-designed RCTs is required to provide meaningful evidence on the effectiveness (absolute and relative) of iontophoresis for the management of LET.

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