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An alternative approach to treating lateral epicondylitis. A randomized, placebo-controlled, double-blinded study

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Objective: To investigate the effect of noxious level electrical stimulation on pain, grip strength and functional abilities in subjects with chronic lateral epicondylitis.
Design: Randomized, placebo-control, double-blinded study.
Setting: Physical Therapy Department, North Georgia College and State University.
Subjects: Eighteen subjects with chronic lateral epicondylitis between the ages of 24 and 72 years participated in this study. Subjects were randomly assigned into treatment or placebo groups.
Interventions: Subjects received six sessions of low-frequency electrical stimulation over the palpated tender points. The intensity of electrical stimulation was set at 0 in the placebo group.
Main measurements: Grip strength, functional status, pain intensity and limited activity due to pain were assessed before and after treatment. Six-month follow-up data were collected in treatment group only.
Results: Both clinically and statistically significant improvements in average grip strength were found (treatment group: 28% increase; placebo group: 2.5% decrease; $P=0.04$), functional activity (treatment group: 110% increase; placebo group: 22% increase; $P=0.003$), pain intensity (treatment group: 3.1 point decrease; placebo group: 0.2 point increase; $P=0.01$) and activity limitation due to pain (treatment group: 4.1 points increase; placebo group: 1.9 point decrease; $P=0.003$) between the treatment and placebo groups. Follow-up data showed that 100% of subjects maintained the improved function, and 83% remained pain-free for at least six months post treatment.
Conclusion: The results of this study indicated that symptoms of chronic lateral epicondylitis could be effectively treated by noxious level low-frequency electrical stimulation.

Introduction

Lateral epicondylitis, also known as tennis elbow, is a pathology characterized by pain over the lateral aspect of the elbow, occurring in 1–3% of the population.[1,2] The highest incidence of diagnosed lateral epicondylitis, about 14%, was associated with work-related activities that involve repetitive and forceful wrist and hand functions.[3–5]

In spite of extensive research on this ailment, there is no general agreement on the precise aetiology and pathophysiology of lateral epicondylitis. Cyriax[6] attributed the symptoms of lateral epicondylitis to microscopic tears of the common extensor tendon at its attachment to the

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lateral epicondyle,[6] which is still accepted as a common cause of the disorder.[2,7–9] This theory, however, does not explain the chronic cases. Most muscle injuries are expected to heal in 3–5 days after injury,[10] while tendon injuries, due to decreased vascularization, may take up to five weeks to heal.[10] Symptoms of lateral epicondylitis, due to the inflammation secondary to soft tissue tears, therefore, should resolve within a five-week period. However, many cases of lateral epicondylitis extend beyond the normal tissue healing timeline into the chronic stages.

More than 40 treatment methods have been recommended for lateral epicondylitis.[11] Overall, conventional treatments emphasizing the reduction of tissue inflammatory reactions, have failed in 10–30% of the cases in reported studies.[2,12,13] In a meta-analysis of 185 research reports by Labelle *et al.*,[14] only 18 randomized controlled studies on treatment of lateral epicondylitis were found. Due to the variability of the outcomes and limited numbers of quality studies, the authors suggested that more randomized controlled trials are needed to determine the efficacy of suggested conventional treatments. Bisset and co-workers[15] performed a systematic review and meta-analysis of 76 randomized controlled trials on the effectiveness of various conventional treatments on lateral epicondylitis. They concluded that conventional treatments failed to provide a long lasting effect on the symptoms.

As an alternative pathophysiology, Chop[2] suggested that some of the symptoms of lateral epicondylitis could be due to tender points developed in the lateral elbow area following overuse or forceful wrist and arm activities. Chaitow[16] attributes the development of such tender points to increased sensitivity of neural receptors in the muscle and its related connective tissue in response to overuse or sudden changes in muscle length after prolonged contractions in a shortened position. Localized tender points in the lateral elbow area could elicit pain when palpated, stretched or overloaded during a strong muscle contraction or repetitive and forceful wrist and elbow movements.[16,17]

Noxious level electrical stimulation has been used for trigger point treatments without any known anti-inflammatory effects.[18,19] Introducing interventions proposed solely for trigger point treatment could validate the aforementioned hypothesis and could provide a viable alternative treatment for lateral epicondylitis. The purpose of this study, therefore, was to examine the effect of noxious level electrical stimulation on symptoms of chronic lateral epicondylitis. We hypothesized that tender point treatment by noxious level electrical stimulation would improve grip strength, pain intensity, functional ability and limitation of activities due to pain in subjects with chronic lateral epicondylitis.

Methods

Design of the study

A randomized, placebo-controlled, double-blinded design was utilized in this study. Two separate physical therapists performed measurements and treatments. One therapist (examiner) conducted screening and measurements, and the other (treating therapist) performed the treatments. Following pretest measurements by the examiner, subjects were randomly assigned into treatment or placebo groups by the treating therapist. Randomization was performed by having subjects draw a card out of a set of cards marked 'Group A' or 'Group B'. Subjects in group A received true treatments (Figure 1). Both subjects and the measuring therapist were blinded to the subjects' group assignments. The treating therapist was blinded to the treatment outcomes throughout the entire data collection period.

Subjects

A total of 18 subjects between the ages of 24 and 72, recruited through advertisement in the North-East Georgia community, participated in this study. Almost all subjects were involved in heavy or repetitive arm movements either as part of their job or during recreational activities. All subjects reported previous unsuccessful treatment, ranging from rest, conventional physical therapy and steroid injections, prior to their participation in this study. Subjects were not receiving any other form of treatment at least three months prior to and during the course of this study.

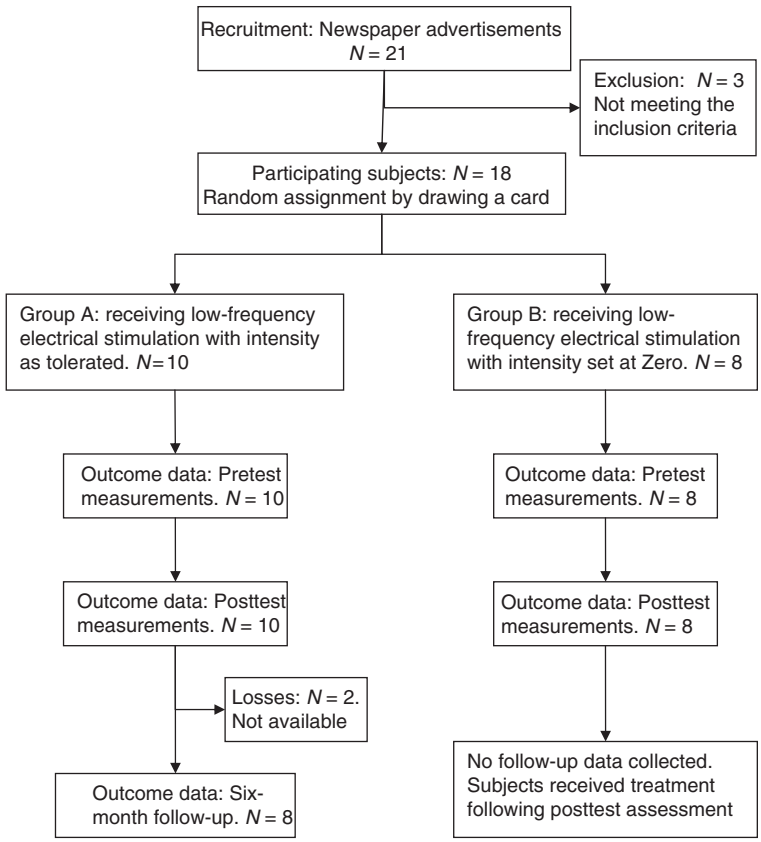

Figure 1 Flow diagram for the study.

Prior to their participation, all subjects were screened by the examiner for proper diagnosis of lateral epicondylitis and to rule out other pathologies that could possibly contribute to lateral elbow pain. Subjects with a history of cervical pathology, nerve entrapment syndromes, non-union fractures, surgical treatments for lateral epicondylitis, and steroid injection for elbow pain during the last six months prior to the study were excluded. The subjects' diagnosis of lateral epicondylitis was confirmed through Cozen's, Mill's and third finger extension tests,[20] and palpation of the origin of the wrist and hand extensors on the lateral epicondyle.

Regardless of their group assignment, all the subjects participating in the study were told that if their symptoms did not improve, they would receive an alternative treatment post test. All subjects signed an informed consent form approved by the Institutional Review Board of North Georgia College and State University.

Materials

The following instruments were used in this study:

- A calibrated Jamar Hand Dynamometer (Sammons Preston, Bolingbrook, IL, USA) was used to measure grip strength in the affected arm. The reliability and validity of this method has previously been established.[21,22] Maximum grip strength was measured three times. The average value of the three measurements was used for data analysis.

- An adapted Patient-Specific Functional Scale was used to measure changes in subjects' functional abilities.[23] The scale requires the subjects to list three activities most affected by their injury. The level of difficulty for each activity is rated on a scale of 0–10, with 0 indicating having most difficulty and 10 denoting their ability to perform the task as well as prior to the injury. The sum of the scores for the three activities quantifies their functional status at each testing period. Good to excellent reliability and validity has been reported for the Patient-Specific Functional Scale in patients with neck, low back and knee injuries.[23–25] Using the Patient-Specific Functional Scale in patients with knee problems, a minimum of 2.5 points change in the scale score is considered to be the minimum clinically important difference. The reliability of the Patient-Specific Functional Scale for elbow injuries has not been previously reported. Therefore, a within-study reliability assessment was conducted, the results of which are reported in the Results section.
- The Numeric Rating Scale was used to assess subjects' pain intensity and limitation of activities due to pain during the last 24 hours before testing.[23,26,27] For pain intensity, subjects rated their pain level on an 11-point scale, with 0 indicating no pain and 10 indicating intolerable pain. According to Spadoni and co-workers,[28] pain reduction greater than 3.0 units in the Numeric Rating Scale, are considered clinically significant. A similar 11-point scale was used to assess limitation of activity due to pain, with 0 representing severely limited and 10 representing no limited activities due to elbow pain.[23]
- Noxious level electrical stimulation was delivered by an MRL Neuroprobe System V (CR Kesner Company, Geneva, IL, USA).

Procedure

Reliability assessment for the Patient-Specific Functional Scale

Intraclass correlation coefficient (ICC 3,1) was used to determine the reliability of the Patient-Specific Functional Scale adapted for use with elbow injuries. Ten subjects (7 men and 3 women) were included in this reliability assessment. After the initial functional assessment, subjects were asked to complete a second Patient-Specific Functional Scale survey at a different scheduled time prior to initiation of their treatment.

Noxious level electrical stimulation treatment

During treatment, the subject was seated with the affected arm resting on the treatment . Following palpation of the painful area on the lateral epicondyle while the subject was holding a ground electrode in his or her affected hand, the therapist searched the area of the lateral epicondyle with the probe electrode to localize a tender point. Upon locating a tender point, electrical stimulation (4 Hz, interrupted DC current) was applied for 30 seconds to the point. The stimulation intensity was adjusted to the subject's pain tolerance level. All identified points, at each treatment session, were stimulated three times. During the treatment period, the subject could hear a beeping tone signifying that a stimulus was being delivered. All subjects received six treatment sessions over a 2–3 week period. Subjects did not receive any other form of treatment including patient education or home exercise programme.

Placebo treatment

Subjects in the placebo group underwent the exact procedure explained above. The only difference was that during the treatment phase when the subjects could hear the beeping tone, suggesting a treatment is being delivered, the stimulus intensity was kept at zero. Although no actual treatment was provided, the subjects were unaware they were in a placebo group.

Data analysis

In addition to the random assignment of subjects into treatment and placebo groups, to assure equality of baseline measures independent *t*-tests were used to compare means of baseline grip strength, functional level, pain intensity and pain-limited activity between the treatment and placebo groups. Multivariate analysis of variance (MANOVA) was used to compare improvements

(subtracting posttest measures from pretest measures) observed in the four dependent variables, between the treatment and placebo groups.

Follow-up study

Follow-up data were collected from eight subjects in the treatment group through phone interviews six months post treatment. Two subjects could not be located for follow-up interview. The same questionnaires related to functional abilities (Patient-Specific Functional Scale), pain intensity (Numeric Rating Scale) and limitation of activity due to pain (Numeric Rating Scale) were used to collect the follow-up data.

Results

Subjects

There were 10 subjects (5 men and 5 women), aged between 24 and 69 years old (mean 50.8, SD = 12.3) with 23.1 months mean duration of symptoms (min = 6, max = 60 months) in the treatment group; and 8 subjects (5 men and 3 women), aged between 41 and 72 years old (mean 51.3, SD = 11.0) with 14 months mean duration of symptoms (min = 3, max = 60 months) in the placebo group. Among all the subjects there were six farmers, four housewives, four retired but involved in recreational sports, one musician, one nurse, one policeman and one basketball couch.

Reliability assessment

Good reliability, ICC = 0.76, was found using the Patient-Specific Functional Scale survey in this study. Statistical analysis of pretest data showed no significant difference in any of the baseline measures for grip strength ($P = 0.91$), functional level ($P = 0.27$), pain intensity ($P = 0.65$) and pain limited activity ($P = 0.18$) between the treatment and placebo groups.

Treatment and placebo group comparison

Figure 2 compares the difference in the amount of improvement observed for each dependent variable in the treatment and placebo groups. MANOVA showed a significant difference in grip strength ($P = 0.04$), pain intensity ($P = 0.01$), limited activity due to pain ($P = 0.003$) and functional level ($P = 0.01$) between the treatment and placebo groups. Detailed information related to each group is presented in Table 1.

Follow-up analysis

Of the eight subjects contacted for follow-up assessment through phone interview, all cases (100%) maintained posttreatment improvements in activity limitation due to pain. Six subjects (75% of the cases) maintained posttreatment improvements in pain intensity and five subjects (63% of the cases) maintained posttreatment improvements in functional abilities.

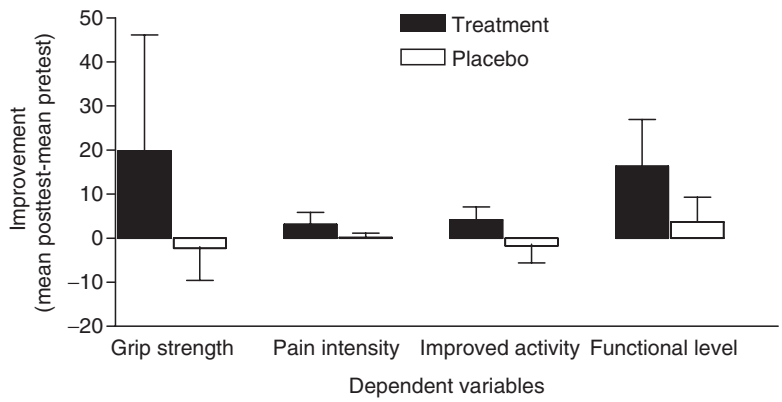

Figure 2 Level of improvements in the tested variables between treatment and placebo groups.

Table 1 Multivariate analysis for comparing improvement in the dependent variables between treatment and placebo groups

Variable	Group	Pretest Mean (SD)	Posttest Mean (SD)	Improvement (pretest–posttest) Mean (SD)	*P*-value (MANOVA)
Grip strength	Treatment	70.4 (27.4)	90.2 (33.2)	19.8 (26.3)	0.04
	Placebo	91.5 (36.4)	89.2 (33.7)	–2.3 (7.3)	
Pain intensity	Treatment	4.2 (2.4)	1.1 (1.5)	–3.1 (2.8)	0.01
	Placebo	3.85 (2.8)	4.0 (2.8)	0.15 (1.0)	
Functional level	Treatment	14.6 (10.1)	30.9 (5.7)	16.3 (10.6)	0.013
	Placebo	17.0 (9.0)	20.8 (11.6)	3.8 (5.6)	
Pain-limited activity	Treatment	5.1 (3.0)	9.2 (1.3)	4.1 (2.9)	0.003
	Placebo	7.1 (2.6)	5.2 (2.9)	–1.90 (3.9)	

Discussion

The results of this study indicated that treating tender points over the lateral epicondyle with low-frequency hyperstimulation could clinically improve pain, grip strength, limited activity due to pain and functional activities in subjects with chronic lateral epicondylitis. These findings could support the hypothesis that the symptoms of chronic lateral epicondylitis might be due to active tender points[2] than due to inflammatory reactions.

The results of this study showed a significant reduction ($P = 0.01$) in pain intensity in subjects in the treatment group compared with those in the placebo group. According to Spadoni and co-workers,[28] pain reduction greater than 3.0 points in the Numeric Rating Scale are considered clinically significant. Therefore, our findings of average 3.1 units decrease in pain intensity in the treatment group compared with almost no improvement (0.15 units) in the placebo group indicate both statistically and clinically a significant effect of treatment on reducing pain intensity in subjects with chronic lateral epicondylitis. Data related to individual subjects revealed that 60% of the cases in the treatment group demonstrated more than 3.0 points reduction in pain intensity following treatment. None of the subjects in the placebo group showed pain reduction of more than 2.0 points after treatment. These findings are similar to those reported in other studies using other forms of hyperstimulation for pain reduction.[29–31]

The significant improvement in grip strength found in this study could be related to decreased pain and improved functional activities in subjects in the treatment group. Pain and tenderness in the wrist extensor muscles working as wrist stabilizers in synergy with the finger flexor muscles[3] could affect the grip strength. According to Vicenzino[32] early pain relief, as was found in this study, could have motivated the subjects to use their arm more often during daily activities, resulting in improved muscle strength. Similar results have been reported using conventional physical therapy treatments,[12,32–38] steroid injection[30,39] or elector acupuncture[40] for treatment of lateral epicondylitis. Other investigators, however, have reported no significant changes in grip strength in patients treated for lateral epicondylitis.[41–46] Conflicting reports of improvement in grip strength after providing different treatments or even in studies using the same treatments[30,39,41] may suggest that the possibility of improvement in grip strength could be related to which muscle in the extensor group is being affected. Pienimaki and co-workers[47] showed that in subjects with lateral epicondylitis changes in grip strength were associated more with having a positive Cozen's test than with having a positive Mill's test in the preliminary evaluation. Contraction of wrist extensors is required to contrast with flexion moment acting on the wrist induced by finger flexors, maintaining the functional position of the wrist during forceful grip. With reduced pain in the origin of the wrist extensor muscles the stabilizing function of these muscles improves, which in turn enhances

mechanical advantage of the finger flexors, and results in a stronger grip.

Improvement in pain and grip strength could explain our findings of significant improvement in functional activities and using the affected arm during daily activities. In this study the treatment group demonstrated a significant improvement in activity tolerance for the previous 24 hours (mean = 4.1 unit improvement) while the placebo group demonstrated minimal decrease in activity tolerance (mean = 1.8 unit decrease). The Patient-Specific Functional Scale provides additional evidence of functional improvement in this study. The treatment group demonstrated a significant ($P = 0.01$) improvement in functional abilities (mean improvement = 16.3 points) compared with the placebo group (mean improvement = 3.8 units).

Improved symptoms of lateral epicondylitis with using noxious level, low-frequency electrical stimulation, without any known anti-inflammatory effects,[19,29] indicates that symptoms of chronic lateral epicondylitis could be due to tender points in the muscles and soft tissue in the lateral elbow area. Tender point development is attributed to gamma set or to neural hypersensitivity[16] in the affected area. With application of noxious level electrical stimulation to the affected area, the nervous system, through the central and peripheral pain control mechanisms, releases inhibitory neurotransmitters which in turn reduce neural hypersensitivity (tender points) in the affected area.[18,48,49] In agreement with others,[19] the results of this placebo-controlled study suggest that the effects of noxious level stimulation on pain control have a neurophysiological rather than psychological basis.

Conclusion

This study has demonstrated that using low-frequency hyperstimulation could result in both clinically and statistically significant improvement in pain, grip strength, function and activity tolerance in subjects with chronic lateral epicondylitis. Based on the findings in this study it can be assumed that symptoms of lateral epicondylitis could be due to active tender points rather than inflammatory reactions.

Limitations

Despite a strong randomized placebo-control, double-blinded design, the authors acknowledge some weakness in this study. This study used a small sample size. Although the results showed significant improvements in the treatment group, a larger sample size would improve the generalizablility of the findings. In addition to random assignment, statistical analysis showed no significant difference between the treatment and placebo groups at baseline. The difference in variability between the two groups, although not statistically significant, could have had some effect on the outcomes of this study. Therefore, further studies are needed to evaluate the effect of other modalities or manual techniques used for trigger point treatments on symptoms of lateral epicondylitis in a larger sample.

Clinical messages

- The results of this study provide an alternative treatment for symptoms of chronic epicondylitis. Other randomized studies with larger sample size could confirm the findings of this study as an effective treatment for lateral epicondylitis.
- Symptoms of lateral epicondylitis could be due to active tender points in the soft tissue surrounding the lateral epicondyle.
- Treating the tender points over the lateral epicondyle and surrounding soft tissue with low-frequency noxious level electrical stimulation could provide a long-lasting effect on improving grip strength, functional activity and reducing pain and limited arm use in patients with chronic lateral epicondylitis.

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Competing interest and source of funding

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Contributions

The primary author was involved in planning and design of the study, providing the treatment, statistical analysis of data and writing of the manuscript. The second author was involved in screening of the subjects and data collection.

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