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RESEARCH REPORT

# Efficacy of low-energy extracorporeal shockwave therapy and a supervised clinical exercise protocol for the treatment of chronic lateral epicondylitis: A randomised controlled study

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**KEYWORDS**
extracorporeal shockwave therapy;
lateral epicondylitis;
supervised exercise protocol

**Abstract** This randomised controlled trial was designed to evaluate the efficacy of low-energy extracorporeal shockwave therapy with a supervised exercise protocol for the treatment of chronic lateral epicondylitis. Thirty patients of lateral epicondylitis were randomly placed into two groups: an experimental group ($n = 15$) and a control group ($n = 15$). The experimental group received low-energy extracorporeal shockwave therapy and supervised exercise once a week for 3 weeks, whereas the control group received a supervised exercise protocol three times a week. Both the groups were instructed to carry out a home exercise programme twice daily for 4 weeks.

Outcome parameters included in this study were pain intensity, pain-free grip strength, and the Disability of Arm, Shoulder, and Hand questionnaire. Data were collected at baseline and after the end of treatment (at 4th week). There was a decline in pain, and improvements in pain-free grip strength and limb function in both groups compared with the baseline values. At the end of the treatment period, the experimental group had greater reduction in pain intensity and better improvement in limb function ($p < 0.01$). It can be concluded that low-energy extracorporeal shockwave therapy, when combined with regular exercise, is an effective method for reducing pain and improving upper limb function in patients with chronic lateral epicondylitis.


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## Introduction

Lateral epicondylitis is defined as a pathologic condition of the wrist extensor muscle at their origin at the lateral epicondyle of the humerus. It includes pain and local tenderness over the common extensor origin, which is exacerbated by continual use [1]. Lateral epicondylitis, often called tennis elbow, is one of the most common lesions of the arm [2]. It is a work-or sports-related pain disorder usually caused by excessive, quick, monotonous, repetitive eccentric contractions and gripping activities of the wrist [3–5].

The basic anatomical cause is sudden and, often repeated, use of the forearm extensor muscles leading to pathological changes mainly in the extensor carpi radialis brevis [4–6]. The extensor carpi radialis brevis tendon has a unique anatomic location that makes its undersurface vulnerable to contact and abrasion against the lateral edge of the capitellum during elbow motion [7].

A wide array of physiotherapy treatments have been recommended for the management of lateral epicondylitis, which have different theoretical mechanisms of action but the same aim of pain relief, control of inflammation, promotion of healing, rehabilitation, and prevention of recurrence [6,8–12]

One of the most common physiotherapy treatments for lateral epicondylitis is the exercise programme [13–15]. Home exercise programmes as well as supervised exercise programmes have been investigated and found to be effective in the treatment of lateral epicondylitis [16]. Strengthening and stretching exercises are the main components of an exercise programme because both strength and flexibility of the muscle/tendon should be addressed [12,15,16]. Stasinopoulos et al [16,17] suggested that exercise programmes should be administered for at least 4 weeks.

Low-energy extracorporeal shockwave therapy is an upcoming modality of treatment for chronic lateral epicondylitis [18–21]. Its use in the treatment of lateral epicondylitis has shown some encouraging results [21,22], but the optimal treatment dose of shockwave therapy has not yet been discovered [8] and inconsistent results have been reported [8,19,20]. The latest *Cochrane Database of Systematic Reviews* suggested that low-energy extracorporeal shockwave therapy provides minimal or no benefit in terms of improving pain and limb function among patients with lateral epicondylitis, when compared with placebo [20]. So far, no study has investigated the effects of combining low-energy extracorporeal shockwave therapy along with a structured exercise protocol for the treatment of chronic lateral epicondylitis.

The objective of this study was to examine whether adding low-energy extracorporeal shockwave therapy to an exercise protocol had any additional effect in the treatment of chronic lateral epicondylitis.

## Methods

### Study design

This was a randomised controlled trial designed to investigate the effect of low-energy extracorporeal shockwave therapy combined with a supervised clinical exercise protocol for the treatment of chronic lateral epicondylitis.

### Participants

The criteria for inclusion were as follows: all referred and prediagnosed cases of lateral epicondylitis, presence of symptoms for ≥6 months, presence of pain on palpation at lateral epicondyle; positive Thomsen test, and positive Maudsley's test. Ethics approval of the study was granted by the Institutional Ethical Committee. Prior to participation in the study, informed consent was obtained from the participants. They were screened according to the inclusion criteria. Maudsley's test was performed with the participants sitting in a chair with the shoulder joint flexed to around 60°, elbow extended, and forearm pronated. The patient was then asked to extend the middle finger against resistance. Positive test was indicated by the presence of pain at the lateral epicondyle area [23]. Thomsen test or resisted wrist extension was performed with the shoulder flexed to 60°, elbow extended, forearm pronated, and wrist extended to about 30°; pressure was applied to the dorsum of the second and third metacarpal bones in the direction of flexion and ulnar deviation to stress the extensor carpi radialis brevis and longus. Positive test was indicated by pain at the lateral epicondyle [21,23].

### Randomisation

After baseline data collection, the participants were then allocated to either the experimental group (Group A) or the control group (Group B) using computer-generated random numbers. Group A consisted of 15 patients (8 women and 7 men) with a mean age of 41.9 years. Group B comprised 15 patients (10 women and 5 men) with a mean age of 42.9 years. All patients in both the groups were treated in isolation so that no patient could know the treatment allocation of other participants. The patients were reassessed at the end of the 4th week (Fig. 1).

### Interventions

The experimental group received low-energy extracorporeal shockwave therapy and supervised exercise once a week for 3 weeks, whereas the control group received same type of supervised exercise programme as that of the experimental group three times a week. All participants in both the groups were instructed to carry out a home exercise programme twice daily for 4 weeks.

For the low-energy extracorporeal shockwave therapy, three sessions of treatment, consisting of 2000 impulses of 0.06 mJ/mm$^2$, were administered to the anterior aspect of the lateral epicondyle and around this site at a radius of 1.5–2 cm at intervals of 1 week [21,22,24]. The low-energy extracorporeal shockwave therapy was applied by an experimental device, the MP-100 model (Storz Medical, Tägerwilen, Switzerland). The treatment head of the device was directed perpendicularly to the point of maximal tenderness on the lateral epicondyle, as identified by the therapist's palpation and patient report. During the

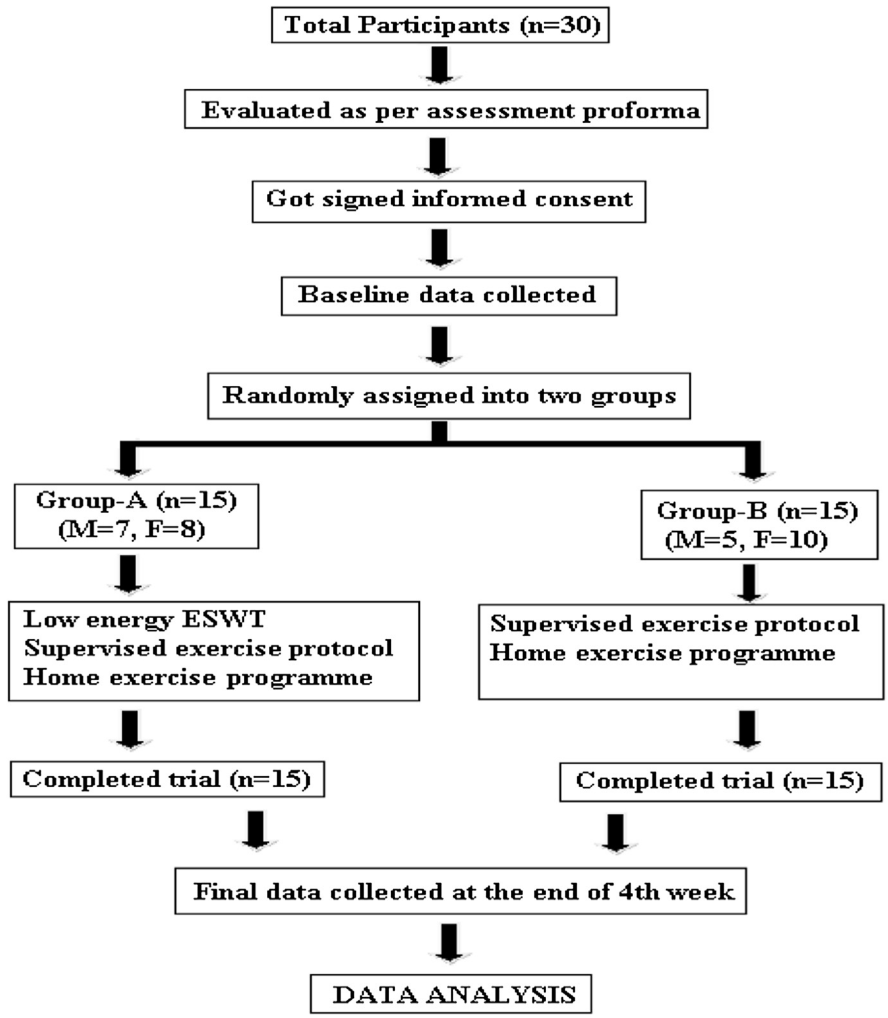


**Figure 1** Study flowchart. ESWT = extracorporeal shockwave therapy; F = female; M = Male.

procedure, a conducting gel was applied to the site of pain, and the treatment head was moved in a circular fashion. During treatment, the technique of clinical focusing was used by adjusting the shockwave focus [24].

The exercise programme consisted of a supervised exercise programme and a home exercise programme. Strengthening and stretching exercises were the main components of the supervised exercise programme. Three forms of musculotendinous contractions (isometric, concentric, and eccentric) were suggested to strengthen the soft tissue structures [25,26]. Stretching exercises were carried out by asking the patients to perform elbow extension, forearm pronation, and wrist flexion with ulnar deviation as tolerated [16,25–28]. Stretching exercises were repeated six times, three times prior to and three times after the strengthening exercises during each treatment session. A 30-second hold and 30-second rest interval was given between the repetitions [14]. The home exercise programme, on the other hand, was demonstrated by the investigator to both the groups in the first session; all patients were given a written "Instruction & exercise booklet" with pictorial illustrations to carry out the exercises at home twice daily regularly for 4 weeks, then once daily for at least 3 months or until symptoms were relieved [29,30].

## Outcome measurement

Pain intensity, pain-free grip strength, and hand function were used as the outcome measures of this study. All outcomes were measured at the initial visit and at the end of 4th week. Pain intensity was measured using a Visual Analogue Scale (VAS). The English version of the Disabilities of Arm Shoulder and Hand (DASH) questionnaire was used to assess hand function. The DASH questionnaire, which was introduced by the American Academy of Orthopedic Surgeons in collaboration with a number of other organisations, is a measure of upper-extremity specific outcomes and has high internal consistency [31,32]. It consists of 30-items, scoring from 0 (no disability) to 100 (severe disability) [31,33]. Pain-free grip strength was measured by a modified sphygmomanometer (Novaphon300, New Delhi, India). The pain-free grip strength, which was recorded in millimetres of mercury (mmHg), was converted to kilograms (kg) using the following formula: sphygmomanometer

**Table 1** Patient characteristics

| Variables | Group A ($n = 15$) | Group B ($n = 15$) | $p$ |
|---|---|---|---|
| Age (y) | 41.9 ± 4.5 | 42.9 ± 5.3 | 0.593 |
| Gender (male/female) | 7/8 | 5/10 | 0.273 |
| VAS | 6.1 ± 0.6 | 6.3 ± 0.8 | 0.491 |
| Pain-free grip strength (kg) | 10.7 ± 3.7 | 10.1 ± 2.1 | 0.584 |
| DASH questionnaire | 72.3 ± 11.6 | 76.3 ± 12.6 | 0.360 |

Mean ± SD indicated unless stated otherwise.
DASH = Disabilities of Arm, Shoulder, and Hand; SD = standard deviation; VAS = Visual Analogue Scale.

score in mmHg × 0.154 − 0.865 = sphygmomanometer score in kg [34].

## Statistical analysis

Statistical analysis was carried out using SPSS 15.0 software (SPSS Inc., Chicago, IL, USA). Patient demographics (e.g., age and gender) at baseline were analysed using $t$ test or chi-square test, depending on the level of data. Paired $t$ test was used to study the changes of VAS score and pain-free grip strength over time in each group. The Wilcoxon signed rank test was used to study the changes in DASH score over time in each group, whereas the Mann—Whitney $U$ test was used to measure those differences in both groups at baseline and at 4th week. A statistically significant difference was defined as $p < 0.025$.

## Results

A total of 30 individuals participated in the study, 15 being randomly allocated to the experimental group (Group A) and another 15 to the control group (Group B). Between-group comparison of participants' age and gender showed no significant difference ($t = -0.541$, $p = 0.593$, and $\chi^2 = 1.200$, $p = 0.273$, respectively) (Table 1). There was also no significant difference in VAS, grip strength, and DASH scores between the two groups at baseline (Table 1). There were no withdrawals, meaning that all 30 recruited patients completed the course of the assigned therapy.

In both groups, there was statistically significant reduction in pain intensity, as indicated by the VAS score from baseline to 4th week ($p < 0.001$). The mean improvement was 4.3 in Group A and 3.5 in Group B (Table 2). Between-group comparison at 4th week revealed that Group A had significantly lower VAS score than Group B ($p < 0.001$) (Table 3).

Pain-free grip strength also showed significant improvement from baseline to 4th week in both groups ($p < 0.05$). The mean improvement was 4.1 in Group A and 1.6 in Group B. There was a tendency for greater improvement of pain-free grip strength in Group A, but the difference did not quite reach statistical significance ($p > 0.025$) (Table 3). Similarly, both groups demonstrated improvements in hand function, as measured by the DASH score over time. The mean improvement was 28.3 in Group A, and 17.2 in Group B (Table 2). As a result, Group A had significantly lower DASH score than Group B at the end of 4th week ($p = 0.001$) (Table 3).

## Discussion

The results of the study demonstrated that a combination of low-energy extracorporeal shockwave therapy and exercise brought greater gains in all the outcome variables than exercise alone.

The between-group comparisons showed significantly greater reduction of pain intensity in the experimental group (69%) than in the control group (56.0%), thus demonstrating that the added low-energy extracorporeal shockwave therapy had a therapeutic effect on pain relief. Rompe et al [21] have hypothesised that there is an overstimulation of nerve fibres resulting in an immediate analgesic effect (hyperstimulation analgesia). It has also been documented by other investigators that application of low-energy extracorporeal shockwave therapy leads to pain relief by direct stimulation of the healing process, neovascularisation, disintegration of calcium, and neural effect. These may involve alterations of the cell membrane permeability, preventing the development of potentials to transmit painful stimuli, direct suppressive effects on nociceptors, and hyperstimulation mechanism that blocks the gate control mechanism [35—37], but these possibilities remain speculative. The exact mechanism of pain relief is still unknown, as concluded by Speed [35] and Radwan et al [38].

In the control group, noticeable improvement in pain level may be due to the beneficial effect of the exercise protocol. Many studies have claimed that exercise is an effective treatment for tendinopathies [39,40]. Stretching exercises help align the collagen fibres and improve tensile

**Table 2** Within-group comparison of outcome variables

| Variable | Group A | | $p$ | Group B | | $p$ |
|---|---|---|---|---|---|---|
| | Pretest | Post-test | | Pretest | Post-test | |
| VAS | 6.1 ± 0.6 | 1.9 ± 0.8 | <0.001* | 6.3 ± 0.8 | 2.8 ± 0.9 | <0.001* |
| Pain-free grip strength (kg) | 10.7 ± 3.7 | 14.8 ± 5.4 | <0.001* | 10.1 ± 2.1 | 11.6 ± 2.0 | <0.001* |
| DASH questionnaire | 72.3 ± 11.6 | 43.9 ± 8.0 | 0.001* | 76.3 ± 12.6 | 59.1 ± 12.3 | 0.001* |

Mean ± SD indicated unless stated otherwise.
*Significant difference between pre-test and post-test ($p < 0.025$).
DASH = Disabilities of Arm, Shoulder, and Hand; SD = standard deviation; VAS = Visual Analogue Scale.

Table 3 Between-group comparisons of outcome variables post-test

| Variables | Post-test | | $p$ |
|---|---|---|---|
| | Group A | Group B | |
| VAS | 1.9 ± 0.8 | 2.8 ± 0.9 | 0.005* |
| Pain-free grip strength (kg) | 14.8 ± 5.4 | 11.6 ± 2.0 | 0.043 |
| DASH questionnaire | 43.9 ± 8.0 | 59.1 ± 12.3 | 0.001* |

Mean ± SD indicated unless stated otherwise.
*Significant difference between Group A and Group B ($p < 0.025$).
DASH = Disabilities of Arm, Shoulder, and Hand; SD = standard deviation; VAS = Visual Analogue Scale.

strength. Strengthening exercises, on the other hand, reduce forces transferred to the elbow by improving stiffness of the muscle to absorb a greater load [29].

An improvement in pain is accompanied by an increase in grip strength in both groups. Hertling and Kessler [41] have anticipated that painful scar that lies at the tenoperiosteal junction is not sufficiently deformable to attenuate the energy of loading. A number of studies corroborate the finding of grip strength improvement following exercise training. Slater et al [42] claimed the phenomenon of postexercise facilitation for the improvement of grip force. Since few seconds following muscular contraction, excitability of the motor pathways innervating the muscle is increased, thereby facilitating repetitive movements [43]. Similar findings of muscle facilitation were also exhibited by Norgaard et al [44].

In addition to measuring impairments such as pain and grip strength, the level of disability associated with lateral epicondylitis was evaluated by the DASH questionnaire. Some of the items of the questionnaire included opening a tight or new jar, preparing meal, pushing heavy objects, performing heavy household chores, carrying heavy objects, and gardening, for which the participants reported that they either were unable to perform the task or performed with extreme (score = 5) or severe disability (score = 4) at baseline. In between-group comparison, the experimental group had more improvement in DASH score than the control group after the treatment period (Table 3). The better improvement in the functional capacity is mostly likely related to the greater reduction in pain level reported in the experimental group.

## Limitations

This study has several limitations. First, the sample size was small (30 participants), which may explain the nonsignificant between-group difference in grip strength after treatment. Second, the duration of treatment lasted only 4 weeks. Better outcomes would have been obtained, had a longer treatment duration been employed. Third, no long-term follow-up assessment was done despite the fact that participants were asked to carry out the home exercises for at least another 3 months after the course of extracorporeal shockwave therapy was completed. Additionally, a modified sphygmomanometer was used to measure pain-free grip strength. Further study should consider using a dynamometer for more precise measurement of grip strength. Finally, the assessor was aware of the group allocation; this might have caused measurement bias. A double-blinded, randomised, controlled study should be conducted in the future to assess the effect of extracorporeal shockwave therapy further.

## Conclusion

This study showed that adding low-energy extracorporeal shockwave therapy to an exercise programme induced significant treatment effect on reducing pain and improving upper limb function in patients with chronic lateral epicondylitis when compared with exercise alone.

## Funding agency

None.

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