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Efficacy of extracorporeal shockwave therapy in patients with lateral epicondylitis: A randomized, placebo-controlled, double-blind clinical trial

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ABSTRACT

OBJECTIVE: Lateral epicondylitis is a common elbow problem. Although extracorporeal shockwave therapy (ESWT) is widely used in the treatment of lateral epicondylitis, its efficacy is still controversial. Moreover, the number of prospective, randomized, controlled studies in the literature is not sufficient. Here, we intend to investigate the efficacy of ESWT.

METHODS: The study was randomized, placebo-controlled, double-blind, and prospectively planned. Forty patients who met the inclusion criteria were divided into two groups, real ESWT (Group 1, n=20) and placebo ESWT (Group 2, n=20), in a 1:1 randomized closed envelope manner. Patients were evaluated for Patient-Rated Tennis Elbow Evaluation-Turkish Version (PRTEE-T), visual analog scale (VAS) pain scores, and grip and pinching strengths. The evaluation were performed thrice before, at the end of treatment and 1 month after treatment. Both groups were treated with wrist splinting, ice treatment, and rest.

RESULTS: There was no statistical difference between sex and dominant hand in both groups. There was no significant difference in the grasp and pinching strength between the measurements of the groups themselves ($p>0.05$). When examined in terms of VAS scores, only significant changes were found in the actual ESWT group ($p<0.05$). According to the PRTEE-T scores, both groups showed significant changes ($p<0.05$). No significant difference was found between post-treatment and control measures in the grip and pinching power between groups, VAS and PRTEE-T scores before treatment ($p>0.05$).

CONCLUSION: Although pain and functional improvement were more prominent in our patients treated with ESWT than placebo, no statistically significant results were found.

Keywords: Epicondylitis; high-energy shock waves; lateral humeral.

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Lateral epicondylitis (LE) is a common elbow problem and often affects active people aged 30–50 years [1, 2]. The incidence is 4/1000 people per year [3]. The definitive etiology is not fully understood, but it is thought that factors such as overuse injury and direct trauma on the lateral epicondyle play a role in the compulsive wrist extension [4].

The goal in LE treatment is to prevent loading into the arm, reduce pain, accelerate healing, and provide rapid return to daily activities. Despite the availability of many studies on LE treatment in the literature, the most appropriate treatment is still controversial. Different treatment modalities are described in the literature, either alone or in combination. Various treatment modalities such as rest, activity modification and restriction, ice treatment, splinting, oral and topical nonsteroidal anti-inflammatory (NSAI) drugs, physical therapy, acupuncture, local injections (corticosteroids, platelet rich plasma), and

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surgery are applied in LE treatment [5]. However, there is not enough scientific evidence to support the effectiveness of each treatment modality [6].

Extracorporeal shockwave therapy (ESWT) has been widely used in many musculoskeletal problems over the last 25–30 years [7, 8]. Though the exact effects have not been proven, it is suggested that shock waves accelerate tissue healing, reduce calcification, and inhibit pain receptors with denervation [9].

Despite the widespread use of ESWT in the treatment of LE, controversy regarding its efficacy still remains. There are publications in the literature that have different conclusions about the efficacy of ESWT. Furthermore, the number of prospective, randomized, controlled studies in the literature is not enough [10]. For this reason, we aimed to investigate whether ESWT is indeed effective in patients with LE in a prospective, randomized, double-blind, and placebo-controlled study.

MATERIALS AND METHODS

This study included patients who were referred to the orthopedics-traumatology and physical therapy rehabilitation clinic in 2014 and 2015 with the complaint of elbow pain and who were diagnosed with LE. Ethical consent was obtained from the ethics committee of the university, and informed consent form was obtained from each patient. The ethics committee approval number is 2014/35.

The inclusion criteria were as follows: patients aged 18–65 years of age, sensitivity on the lateral epicondyle, positive diagnosis of LE, and no treatment for LE within the last 3 months. The exclusion criteria were the presence of any treatment for LE within the last 3 months, pregnancy, hemostatic disturbance, upper extremity tumor, local or systemic infection, pacemaker attachment, elbow arthritis, posterior interosseous nerve syndrome, and radiculopathy.

The study included 100 patients with complaints of 3 weeks to 1 year who met the following diagnostic criteria. LE was diagnosed with ≥2 of the following prognostic tests with patient complaining of pain in the lateral epicondyle region. The provocative tests used in the study were as follows:

1. Lateral epicondyle sensitivity in palpation.
2. Positive Cozen's test: pain during wrist extension against resistance.
3. Moudley's test: pain during middle finger extension against resistance.
4. Chair test: pain during lifting of weight of approximately 3–5 kg.

This was a randomized, placebo-controlled, double-blind, and prospective study. Forty patients who met the inclusion criteria were divided into two groups, real ESWT (Group 1, n=20) and placebo ESWT (Group 2, n=20), in a 1: 1 randomized closed envelope manner. Treatment and evaluation were done by different physicians. Patients were informed of the intent of studying after the diagnosis of the disease and comparing two separate treatment protocols, and their approval was obtained. Before the application, demographic data of the patients, the duration of illness, the side of complaint, the dominant side, and additional systemic diseases were recorded to the previously prepared forms.

Evaluation

Patients were evaluated with the Patient-Rated Tennis Elbow Evaluation-Turkish Version (PRTEE-T) [11]. The level of pain at rest, compression, and activity were assessed as 0–10 points (0, no pain; 10, very painful) using the visual analog scale (VAS). The Roles and Maudsley score was also taken. Scores were assesed thrice before, at the end of treatment and 1 month after treatment.

Gripping and Pinching Forces Measure

The maximal gripping and pinching forces were measured using Jamar dynamometer before, at the end of treatment and 1 month after treatment. Hand dynamometry (Jamar dynamometer, Preston Healthcare, Jackson, USA) was used for the procedure. The patient was informed about how to perform the measurement with hand dynamometer before the procedure and confirmation regarding their understanding was taken. The measurement was performed by the same physician (SS, MT) who performed the examination. The procedure was performed while sitting in a chair and the forearm was in a comfortable position at 60° flexion on the table. The patient requested a maximum squeeze of the jammer. This process was repeated thrice and the average value was recorded.

ESWT treatment

ESWT procedure was performed by the same physiotherapist (NE). A BTL device (BTL 6000 SWT TOPLINE, UK) was used for ESWT. Without apply-

ing local anesthesia to the marked area, an R15 applicator was used with a hand gun at 1500 pulse counts, a frequency of 15 Hz, and an energy density of 2.4 bar. The peripheral muscles were applied with a D35 applicator tipped hand gun at 1500 pulse counts, using a gel at the interface at an energy density of 1.8 bar and a frequency of 21 Hz. The placebo ESWT group was performing all steps as if it were being done. To be more convincing, the device provided sound at every shock, but no electric current was supplied. Both groups were treated with wrist splinting, ice, and rest, so that the placebo group would not be left without treatment.

Statistical analyses

Statistical analyses were performed using SPSS version 21.0 software. The normal distribution of variables was examined using visual (histogram and probability plots) and analytical methods (Kolmogorov–Smirnov/Shapiro–Wilk tests). The pre-treatment, post-test, and control measures included changes in the groups themselves using the repaired measures ANOVA test. Paired t test was used to assess post-hoc Bonferroni adjustment if the results were significant. The ANCOVA test was used to compare changes between groups. Statistically significant results were obtained when the p-value was <0.05.

RESULTS

The demographic data of the patients are shown in Table 1. There was no statistical difference between sex and dominant hand in both groups. When statistical evaluation was made, changes within the groups themselves were evaluated first. For this, pre-treatment, post-treatment, and control outcomes were assessed using the repaired measures ANOVA test.

There was no significant difference in the grasp and pinching strength between the measurements of the groups ($p>0.05$). Also, there was no statistically significant difference between post-treatment and control measures compared with pre-treatment grip and pinching power among the groups ($p>0.05$).

Regarding VAS scores, significant changes were found in the real ESWT group ($p<0.05$). When examining the extent of this change, it was seen that the changes between pre-treatment and post-treatment control measures were significant ($p<0.05$). There was no significant difference between the groups in terms of VAS scores ($p>0.05$).

According to PRTEE-T scores, both groups found significant changes in themselves ($p<0.05$). It was found that the changes between pre-treatment and post-treatment control measures in the real ESWT group were significant ($p<0.05$). Similarly, in the placebo ESWT group, the changes between before and after treatment and between pre-treatment and control measures were significant ($p<0.05$). However, there was no significant difference between the groups in terms of PRTEE-T scores ($p>0.05$).

Table 1. Collected data

	Real ESWT group		Pseudo-ESWT group	
Sex	6 male, 14 female		6 male, 14 female	
Age	46.3±8.09		45.8±10.8	
BMI	28.6±4.1		27.3±3.4	
Symptom duration (month)	4.1±2.4		4.4±2.2	
Affected side	11 right, 9 left		13 right, 7 left	
	Preatment	Control	Preatment	Control
VAS Score	5.8±1.8	4.3±2.1	6.1±1.6	5.3±1.8
PRTEE-Score	79.7±26.4	60.1±33.2	76.7±19.7	64.7±20.2
Grasping force	45.9±21.8	52.1±19.2	47.05±14.4	49.4±16.07
Pinch force	11.1±5.3	12.5±4.4	11.9±2.6	12.3±3.7

BMI: Body mass index; ESWT: Extracorporeal shockwave therapy; PRTEE: Patient-rated tennis elbow evaluation; VAS: Visual Analog Scale.

DISCUSSION

This study compared actual ESWT and placebo ESWT results in patients with LE. According to our results, early recovery of ESWT treatment improved in grip strength, pinching strength, VAS, and PRTEE-T functional scoring in both groups, although it was more pronounced in the true ESWT group. However, there was no statistically significant difference between the groups in the changes ($p>0.05$). There are studies with similar results in literature [9, 12–15]. In some studies, ESWT is not effective or is even less effective than placebo [9, 12, 14, 16, 17]. Our study differs from these studies for the first time to assess grip strength as well as pinch strength and also to use a LE specific scoring system such as PRTEE-T. Three of these studies have been separated from our study due to chronic LE cases with similar outcomes and to patients after failed non-operative treatment [9, 12, 13].

Haake et al. [12] found that ESWT treatment in a multicenter, randomized, placebo-controlled, single-blind study was not as effective as placebo. The success rate of treatment administered under local anesthesia at 12 weeks was 25.8% in the ESWT group and 25.4% in the placebo group. Although consistent with the results of our study, there are differences in the dose of ESWT and method of application.

In a prospective randomized double-blind study, Melikyan et al. [14] performed high-dose ESWT without local anesthesia, which is similar to that performed in our work. The difference is that the area to be applied ESWT is determined by USG. In this study, no statistically significant difference was found between the groups after 12 months.

In the placebo-controlled study by Speed et al. [9], patients had a mean duration of 15.9 months in the ESWT group and 12 months in the placebo group. Similar to our study, they did not use local anesthesia during ESWT administration. The ESWT doses were applied at a rate of 0.18 mJ/mm^2 at 1500 counts. Significant improvement was observed in the study in both groups over 2 months. However, similar to our study, there was no significant difference in pain scores between the groups.

Rompe et al. [18] used Siemens Sonocur Plus unit device. The ESWT site, as in our study, determined where the pain was at the maximum; however, unlike our study, this study confirmed the point of application using USG. The results of this study are consistent to those in our study. Both groups showed improvement over time. However, no statistically significant difference was found between the groups.

There is still confusion regarding the efficiency of ESWT in the treatment of LE [9, 12–14, 18–20]. Similar results have been reported in the review of Stasinopoulos et al. [10]. The reasons behind the different outcomes can be easily understood by analyzing the methods of the studies. Factors such as the use of different devices, variable doses and protocols, different patient selection criteria, follow-up times, and evaluation methods affect the outcomes of the studies. Therefore, good quality, standardized, prospective, randomized, double-blind studies are needed.

There are also publications reporting the effectiveness of ESWT in the treatment of LE between 68% and 91% [18, 19, 21]. Rompe et al. [19] reported excellent results in 48% of patients in the low-energetic ESWT group and 100% of patients in the placebo-controlled chronic tennis elbow. On the other hand, in the placebo group, 6% and 24% reported acceptable and excellent results, respectively. Again, Rompe et al. [18] found that low-energy ESWT was statistically significantly more effective than the placebo group in our placebo-controlled trial of 78 patients. Wang et al. [21] compared 43 patients who were followed up for 1–2 years in the case series with six disease placebo control groups and achieved close to 90% good results.

In a study by Spacca et al. [22], 31 patients were administered radial shock wave therapy (RSWT) 4 times a month at a rate of 2 beats per month in 31 prospective randomized controlled trials, and the control group was administered RSWT at a rate of 20 beats to 31 patients. Unlike our study, the clinical diagnosis of LE was confirmed by USG or MRI. Similar to this study, local anesthesia was not performed for RSWT. Unlike our study, patients who did not respond to treatment, treated with injection therapy, were included to study. Patients were evaluated thrice before treatment, at the end of treatment, and at the 6th month after treatment. Spacca et al. reported that RSWT is an effective treatment method that can be safely applied in the treatment of LE and is an alternative modality to low-energy ESWT.

The limitations of our study include the number of cases, the short follow-up period, not using an imaging method such as USG or MRI to confirm the diagnosis, and not applying ESWT in USG guideline. For these 1-month follow-ups, Haake et al. [12] led us to hypothe-

ses about spontaneous improvement in pain in the long term. The cost of using USG or MRI for diagnosis confirmation prevented cost and unnecessary work. The reason for using USG during the application was the lack of infrastructure such as the lack of our own USG device in our polyclinic.

As a result, although pain and functional improvement were more prominent in our patients treated with ESWT treatment, no statistically significant differences were found between two groups. However, as per the literature, we think that ESWT can be performed before surgical treatment, especially when there are no local complications in low-energy ESWT and RSWT and the publications that give positive results. However, in the treatment of LE, there is a need for multicenter, placebo-controlled studies investigating the efficacy of ESWT.

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