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Extracorporeal Shock Wave Therapy for Lateral Epicondylitis at Any Stage of Timing of Onset: Effect on Pain, Strength and Function

Lateral Epikondilit için Ekstrakorporeal Şok Dalga Tedavisinin Başlangıç Zamanlamasının Herhangi Bir Aşamasında: Ağrı, Güç ve Fonksiyon Üzerine Etkisi

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ABSTRACT Objective: The aim of this study was to demonstrate the effectiveness of extracorporeal shock wave therapy (ESWT) used in the treatment of lateral epicondylitis (LE) and to determine whether the time since onset of pain has an impact on outcome. **Material and Methods:** The study included 47 patients who were diagnosed with LE and treated with ESWT. The patients were separated as those who had symptoms for <3 months as the acute LE group (n=12), those who had symptoms for 3-6 months as the subacute LE group (n=20) and those who had symptoms for >6 months as the chronic LE group (n=15). The outcome measures were the maximum and rest visual analog scale (VAS) for pain, grip dynamometer for grip strength and patient-rated tennis elbow evaluation (PRTEE) for functionality of the arm. All patients were evaluated pre-treatment, post-treatment and at 1 month after treatment. **Results:** Significant improvements were obtained in VAS maximum, VAS rest and hand grip strength values after treatment and these improvements continued in the follow-up evaluations. In addition PRTEE values were significantly decreased after treatment. Although there was a significant increase in the PRTEE values between the post-treatment and follow-up evaluations, follow-up values were still statistically superior compared to pre-treatment. When patients were grouped according to pain duration, no statistically significant difference was determined in the changes in VAS scores, grip strength and PRTEE scores. **Conclusion:** ESWT is an effective treatment modality in the treatment of LE. It is also an effective treatment method in acute, subacute and chronic stages of LE, and there is no statistically difference between these periods.

Keywords: Lateral epicondylitis; extracorporeal shock wave therapy; acute; subacute; chronic

ÖZET Amaç: Çalışmanın amacı, lateral epikondilit (LE) tedavisinde kullanılan ekstrakorporeal şok dalgası tedavisinin [extracorporeal shock wave therapy (ESWT)] etkinliğini ortaya koymak ve ağrı süresinin tedavinin başarısına etkisi olup olmadığını belirlemektir. **Gereç ve Yöntemler:** Çalışmaya LE tanısı ile ESWT ile tedavisi alan 47 hasta dâhil edildi. Hastalar semptomları 3 aydan daha kısa olanlar akut LE grubu (n=12), 3-6 ay arası olanlar subakut LE grubu (n=20) ve 6 aydan daha fazla olanlar kronik LE (n=15) olarak ayrıldı. Sonuç ölçütleri, ağrı için maksimum ve dinlenme vizüel analog skala (VAS), kavrama gücü için kavrama dinamometresi ve kolun işlevselliği için hasta derecelendirmeli tenisçi dirseği değerlendirmesi [patient-rated tennis elbow evaluation (PRTEE)] idi. Tüm hastalar tedavi öncesi, tedavi sonrası ve tedaviden 1 ay sonra değerlendirildi. **Bulgular:** Tedavi sonrası VAS maksimum, VAS dinlenme ve el kavrama gücü değerlerinde önemli gelişmeler elde edildi ve bu gelişmeler takip değerlendirmelerinde de devam etti. Ek olarak PRTEE değerleri tedaviden sonra önemli ölçüde azaldı. Tedavi sonrası ve takip değerlendirmeleri arasında PRTEE değerlerinde anlamlı bir artış olmasına rağmen takip değerleri tedavi öncesi ile karşılaştırıldığında hâlâ istatistiksel olarak üstündü. Hastalar ağrı süresine göre gruplandırıldığında, VAS, kavrama gücü ve PRTEE puanlarındaki değişikliklerde istatistiksel olarak anlamlı bir fark saptanmadı. **Sonuç:** ESWT, LE tedavisinde etkili bir tedavi yöntemidir. LE'nin akut, subakut ve kronik evrelerinde de etkili bir tedavi yöntemidir ve bu dönemler arasında istatistiksel olarak fark yoktur.

Anahtar Kelimeler: Lateral epikondilit; ekstrakorporeal şok dalga tedavisi; akut; subakut; kronik

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Lateral epicondylitis (LE) is defined as the chronic degeneration of wrist extensor tendons that adhere to the LE region of the humerus and is also known as tennis elbow.[1] It is usually observed in patients aged between 40-50 years and at equal incidence in males and females.[2] It is more frequent in the dominant arm, consistent with overuse as a major causative factor. Although pain is a major problem, grip strength and activities of daily life are highly affected.[3,4] The diagnosis can be made as the pain is aggravated by palpation of the lateral epicondyle region, resistant wrist extension and passive wrist flexion. Although the disease is named epicondylitis, non-inflammatory tissue has been detected rather than inflammatory tissue in most histopathological examinations and it is also referred to as "angiofibroblastic tendinosis".[5] In conservative treatment of LE, medical treatments, rest, cold application, brace and injections (corticosteroid injection, botulinum toxin injection, platelet-rich plasma, stem cells etc.) are frequently used. In addition, physical therapy agents such as electrical stimulation, ultrasound, laser and mobilization, massage, stretching and strengthening exercises are also used in treatment.[6,7] Surgical treatment open extensor carpi radialis brevis (ECRB) release, percutaneous extensor tenotomy and arthroscopic ECRB release is required in some resistant cases.[8]

Extracorporeal shock wave therapy (ESWT) is another alternative conservative treatment method that has been widely used in musculoskeletal diseases in recent years. According to a widely accepted view, the mechanism of this therapy is to increase hyperstimulation and vascularity with acoustic waves focused on a specific area, thereby accelerating healing and reducing pain.[9] Recently, the use of ESWT in the treatment of LE has become increasingly common.

In the literature, many studies reported that ESWT therapy is effective in the treatment of LE. In addition, there are studies reporting that ESWT treatment is superior to many different treatment methods used in the treatment of LE.[10] On the other hand, in some randomized controlled studies, it was reported that ESWT did not provide a significant efficacy compared to placebo in the treatment of LE.[11,12] Therefore, the effect of ESWT treatment on LE is still controversial.

Another topic that is controversial in the literature regarding the use of ESWT in LE treatment is the duration of the disease. Most of the studies on LE have been conducted on chronic cases, and studies revealing the acute-chronic difference are limited and contradictory.[13-16] There is not enough information in the literature to determine whether there is any difference in the effects of ESWT on the acute, subacute and chronic phases of LE.

The aim of this study was to determine the effect of ESWT on pain, grip strength and daily activities in LE disease, and to examine whether the effectiveness of ESWT is different in acute, subacute and chronic cases.

MATERIAL AND METHODS

STUDY DESIGN AND PARTICIPANTS

A retrospective review was made of the medical records of 47 patients with LE (by physicians B.A. and Ö.K.), who were treated with ESWT in our rehabilitation center between May 2017 and May 2019. Demographic and clinical data including age, gender, involved extremity, pain duration, previous treatments, and comorbidities were recorded (Table 1). The patients included in the study were those aged 18-65 years, with a confirmed diagnosis of LE with pain and sensitivity over the lateral epicondyle or Cozen test positivity. Exclusion criteria were defined as a history of elbow trauma or surgery, cervical radiculopathy, forearm or arm fracture, vascular disorder, cardiac pacemaker, or incomplete treatment protocol or follow-up. The study protocol was approved by non-interventional clinical studies ethics committee (Karabük University, 25.09.2020-2020/291). This study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients were classified into groups according to pain duration as acute (0-3 months), subacute (3-6 months) and chronic (>6 months).[17]

TREATMENT PROTOCOL

ESWT therapy was applied using a ShockMaster 500 device (UniphyElektromedizin, Hennigsdorf, Germany), at 10 Hz, 1.8 bar energy density, 2000 pulses, once a week for three sessions using aquasonic gel as

the transmitting medium. This ESWT protocol has been used routinely in our rehabilitation center for many years. The application was performed while the patient was seated with the shoulder at 45° abduction, elbow flexed, and forearm supported in supine position. The target area for application was the most tender point on the lateral epicondyle and surrounding area. No local anesthetic agent or oral/local non-steroid anti-inflammatory drugs (NSAID) were administered.

CLINICAL ASSESMENT

Pain levels of the patients were measured with a visual analog scale (VAS), which was scored from 0 (no pain) to 10 (extremely severe pain). Firstly, VAS at rest were measured and then maximum VAS after resistive wrist extension separately.

Grip strength is a useful objective measurement for the evaluation of disease severity, treatment response, and functional recovery in LE. Grip strength was measured as maximum grip strength with a Jamar Hydraulic Hand Dynamometer (Sammons Preston, Inc., Bolingbrook, IL, USA) while the patient was seated, with the shoulder in neutral position, the elbow in 90^0 of flexion, the forearm and the wrist in a neutral position. A mean value of three measurements was calculated.

Arm function was evaluated with the Patient-Rated Tennis Elbow Evaluation (PRTEE) questionnaire.[18] The PRTEE is a specific assessment tool for LE patients consisting of 15 items and three subscales [pain (five items), specific activities (six items), and daily living activities (four items)]. Higher scores indicate severe disability. Turkish language validation and reliability of this questionnaire have been shown by Altan et al.[19]

The clinical and functional outcomes of all patients were evaluated before therapy, after therapy and at 1 month after treatment.

STATISTICAL ANALYSIS

Data obtained in the study were analyzed statistically using SPSS (Statistical Package for Social Sciences) for Windows vn.22.0 software (SPSS Inc, Chicago, IL). The conformity of variables to normal distribution was examined using visual (histogram and probability graphs) and analytical methods (Shapiro-Wilk test). Descriptive analysis was given as the frequency distribution and percentage for nominal variables, and the median and interquartile width for non-normally distributed variables. Time-dependent repeated measurement analyses of non-parametric variables were applied with the Friedman test. If necessary, double comparisons were made using the Wilcoxon test and evaluated using Bonferroni correction. The Mann-Whitney U test was used in comparisons between the groups. Type-1 error level was set as 5% for statistical significance.

RESULTS

Of 78 LE affected patients treated with ESWT, 31 were excluded (5 with cervical radiculopathy, 2 with elbow trauma, 7 aged >65 years, and 17 did not have sufficient medical records). Evaluation was made of 47 patients, comprising 26 (55.3%) females and 21 (44.7%) males with a median age of 40.0 years, and median pain duration of 5.0 months (Table 1).

There was no statistically significant difference in the demographic data and baseline clinical characteristics of the groups according to pain duration ($p>0.05$) (Table 2).

After treatment, a statistically significant decrease was determined in the VAS maximum and VAS rest values of the patients and these improvements continued in the follow-up evaluations ($p<0.001$). Statistically significant improvements in grip strength after treatment continued in the follow-up evaluations ($p<0.001$). Statistically significant improvements were observed in PRTEE values after treatment but there was a significant increase in the PRTEE value in the follow-up evaluations when comparing with the post-treatment values, it was still statistically superior compared to before treatment. ($p<0.001$) (Table 3).There was no difference in baseline and post-treatment scores regarding the dominant hand.

After treatment, there were no significant differences between the groups in terms of the median changes in VAS maximum and VAS rest at baseline-after treatment and baseline-month 1 ($p>0.05$) (Table 4). There were no significant differences between the groups in respect of median differences in PRTEE score and grip strength at baseline-after treatment and baseline-month 1($p>0.05$) (Table 4).

TABLE 1: Clinical and demographic data of the groups at the baseline.

Age (year), Median (IQR)	40.0 (9.5)
Female, n (%)	26 (55.3)
Extremity held	
Dominant, n (%)	34 (72.3)
Non-dominant, n (%)	13 (27.7)
Pain duration (month), Median (IQR)	5.0 (8.0)
VAS maximum (0-10), Median (IQR)	8.0 (1.0)
VAS rest (0-10), Median (IQR)	4.0 (3.0)
PRTEE, Median (IQR)	67.0 (19.0)
Grip strength (kg), Median (IQR)	23.0 (9.0)

IQR: Interquartile range; VAS: Visual analogue score;
PRTEE: Patient-rated tennis elbow evaluation.

DISCUSSION

The aim of this study was to investigate the effects of ESWT on LE and to determine whether pain duration has an effect on treatment. Significant improvements in pain, grip strength, and functioning of the arm were observed with ESWT in all (acute, subacute and chronic) periods. However, there was no statistically significant difference between the groups.

There are many studies in literature showing that ESWT is effective in the treatment of LE. In these studies, it has been compared with many other treatment agents (exercise, steroid injection, ultrasound, wrist extensor splint) and it has been concluded that ESWT is more effective.[20-22] Radwan et al. reported that ESWT appeared to be a useful non-invasive treatment method that reduced the necessity for surgical procedures.[23] However, despite successful results reported in the literature, there are also clinical case series and randomized controlled trials showing that the effectiveness of ESWT is inadequate and not different from a placebo.[11,12,24] The reason for these different and contradictory results may be the use of different models of ESWT devices and different treatment protocols (number of sessions per week, frequency, number of impulses per session, treatment interval, duration of application, energy of shockwave etc.). Rompe et al. compared low dose and high dose ESWT administration and stated that low dose is not effective in reducing pain.[25] Speed et al. stated that ESWT treatment performed for a total of three sessions, at 1,500 pulses / session monthly, had a placebo effect.[11] In addition, non-steroidal drugs are thought to suppress the inflammatory response produced by ESWT and affect the response to treatment.[26] In the present study, ESWT (10 Hz, 1.8 bar energy density, 2,000 pulses, once a week for three sessions) was implemented and the results were satisfactory. Akkurt et al. also used this protocol and the results were satisfactory like this study.[20] No local anesthetic agent or oral/local NSAID were administered.

Studies investigating the follow-up 1 month later effects of ESWT in the treatment of LE are available in the literature. Bayram et al. reported that 3 sessions of ESWT treatment applied once a week decreased the PRTEE scores statistically at first month.[27] But in this study, assesments were applied on pre-treatment and first months after the treatment and there was no

TABLE 2: Clinical and demographic data of the groups at the baseline.

	0-3 months (n=12)	3-6 months (n=20)	6 months (n=15)	p value
Age (year), Median (IQR)	43.0 (8.25)	38.0 (13.75)	40.0 (18.0)	0.614
Female, n (%)	8 (66.7)	11 (55.0)	7 (46.7)	0.583
Extremity held				
Dominant, n (%)	7 (58.3)	17 (85.0)	10 (66.7)	0.221
Non-dominant, n (%)	5 (41.7)	3 (15.0)	5 (33.3)	
VAS maximum (0-10), Median (IQR)	8.0 (2.75)	8.0 (1.0)	8.0 (1.0)	0.953
VAS rest (0-10), Median (IQR)	4.5 (3.0)	3.5 (3.0)	4.0 (3.0)	0.937
PRTEE, Median (IQR)	63.5 (27.5)	70.0 (14.75)	69.0 (20.0)	0.998
Grip strength (kg), Median (IQR)	21.0 (8.75)	23.5 (8.75)	24.0 (9.0)	0.610

IQR: Interquartile range; VAS: Visual analogue score; PRTEE: Patient-rated tennis elbow evaluation.

TABLE 3: Comparisons of median values of VAS maximum, VAS rest, PRTEE score and grip strength at the baseline, after treatment and month 1.

	Baseline Median (IQR)	After treatment Median (IQR)	Month 1 Median (IQR)	p value
VAS maximum	8.0 (1.0)	4.0 (4.0)*	4.0 (4.0)*	p<0.001
VAS rest	4.0 (3.0)	2.0 (3.0)*	2.0 (3.0)*	p<0.001
PRTEE	67.0 (9.0)	48.0 (13.0)*	54.0 (15.0)*	p<0.001
Grip strength	23.0 (9.0)	27.0 (9.0)*	26.0 (10.0)*	p<0.001

*Difference is statistically significant compared to baseline (p<0.001); IQR: Interquartile range; VAS: Visual analogue score; PRTEE: Patient-rated tennis elbow evaluation.

TABLE 4: Inter-group comparison of median differences of VAS maximum, VAS rest, PRTEE score and grip strength at baseline-after treatment and baseline-month 1.

		0-3 months (n=12)	3-6 months (n=20)	6 months (n=15)	p value
VAS maximum	Baseline-after treatment Median (IQR)	4.0 (2.75)	3.0 (2.75)	2.0 (2.0)	0.368
	Baseline-Month 1 Median (IQR)	3.5 (2.0)	3.0 (3.0)	2.0 (2.0)	0.451
VAS rest	Baseline-after treatment Median (IQR)	2.0 (2.75)	2.0 (2.0)	2.0 (3.0)	0.995
	Baseline-Month 1 Median (IQR)	2.0 (3.50)	2.0 (2.0)	2.0 (3.0)	0.982
PRTEE	Baseline-after treatment Median (IQR)	19.0 (22.75)	16.0 (18.0)	17.0 (10.0)	0.930
	Baseline-Month 1 Median (IQR)	17.0 (23.75)	14.0 (13.75)	17.0 (11.0)	0.964
Grip strength (kg)	Baseline-after treatment Median (IQR)	4.0 (2.75)	4.0 (4.0)	5.0 (5.0)	0.894
	Baseline-Month 1 Median (IQR)	3.5 (3.75)	3.5 (3.75)	4.0 (5.0)	0.868

VAS: Visual analogue score; IQR: Interquartile range; PRTEE: Patient-rated tennis elbow evaluation.

data that comparing the post-treatment and follow-up values. In the study of Yalvaç et al. comparing ESWT and therapeutic ultrasound in the treatment of LE, a statistically significant decrease in PRTEE values were reported in both groups after treatment and one month follow-up.[21] In present study, statistically significant improvements were observed in PRTEE values after treatment. In the one month follow-up evaluations, although there was a significant increase in PRTEE value, it was still statistically superior compared to before treatment. Therefore, it suggests that many studies with longer follow-up may be needed to determine the long-term effects of ESWT.

The timing of ESWT therapy in tendinosis is also controversial in the literature. Khan et al. stated that treatment of early-diagnosed tendinosis should not be later than 6-10 weeks, otherwise treatment may take 3-6 months in cases of chronic disease.[28] Most of the ESWT studies on the treatment of LE have been conducted on chronic cases. There is little information in literature on acute presentations.[13-16] Helbig et al. concluded that ESWT is more effective in patients with pain symptoms ongoing for longer than 35 months.[14] Chung et al. emphasized that patients with a symptom duration of <16 weeks benefited more from ESWT than those with >16 weeks.[15] In studies by Köksal et al. and Stania et al., patients were separated into two groups as acute (<3 months) and chronic (>6 months) according to symptom duration and it was concluded that ESWT had positive effects on LE in both groups.[13,16] There are no studies in the literature on the subacute period of LE (3-6 months). This study is the

only study in which acute (<3 months), subacute (3-6 months) and chronic (>6 months) patient groups have been separately examined and compared with each other. At the end of this study, statistically significant positive effects were determined in pain, grip strength and daily activities in all the ESWT treatment groups, and there was no significant difference between the groups. Therefore, ESWT can be considered to be effective in acute and subacute periods as well as in the chronic period of LE symptoms, and early treatment will decrease the rate of chronicity of cases.

In the treatment of LE, minor complications have been reported that do not require additional treatment. Since low-energy shock waves are used in the treatment, complication rates are not high. Redness of the skin, local temporary pain, petechiae and hematoma are rare complications.[29] In the present study, no side effects were recorded in any patient.

There were some specific limitations in the study, primarily the lack of a control group. The retrospective design, lack of long term follow-up and the small sample size can be considered other limitations.

CONCLUSION

In conclusion, ESWT is an effective treatment modality in the treatment of LE. ESWT improves the pain, strength and function of patients with LE at any stage of symptom onset.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

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