DOI: 10.4274/MMJ.galenos.2024.60308
Medeni Med J 2024;39:109-116

Original Article

Clinical and Sonographic Evaluation of the Effectiveness of Extracorporeal Shock Wave Therapy in Patients with Lateral Epicondylitis

Lateral Epikondilitli Hastalarda Ekstrakorporeal Şok Dalga Tedavisi Etkinliğinin Klinik ve Sonografik Değerlendirmesi

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ABSTRACT

Objective: This study assessed and compare the clinical and sonographic outcomes of extracorporeal shock wave therapy (ESWT) in patients with lateral epicondylitis (LE).

Methods: Forty-two LE patients were randomly divided into two groups: the ESWT group (n=21) and the sham-ESWT control group (n=21). Both groups underwent wrist resting splinting, stretching, strengthening exercises for wrist extensors, and ice application. Grip strength, pain, and functionality were assessed by various tests, and common extensor tendon (CET) thickness was measured sonographically before, after, and 1 month after treatment by a blind examiner.

Results: At baseline, there was no significant difference between the groups. Significant differences were observed in pain pressure threshold, grip strength, visual analog scale, and Patient-Rated Tennis Elbow Evaluation (PRTEE) scores between baseline, post-treatment, and 1 month after treatment in both groups ($p<0.05$). However, the Short Form-12 (SF-12) physical scores showed a significant difference only 1 month after treatment ($p<0.01$). In the SF-12 mental score tests, no significant difference was found. CET thickness in the ESWT group significantly decreased after treatment and 1 month after treatment ($p<0.05$), whereas no significant difference was observed in the control group.

Conclusions: Both the ESWT and control groups showed a reduction in pain and improvement in function. However, the ESWT group showed statistically superior results in terms of pain reduction and functional improvement compared with the control group. In addition, sonographic evaluation revealed a significant reduction in CET thickness in the ESWT group, whereas no significant change was noted in the control group.

Keywords: Lateral epicondylitis, extracorporeal shock wave therapy (ESWT), sonographic assessment

ÖZ

Amaç: Bu çalışmanın amacı lateral epikondilit (LE) tanılı hastalarda ekstrakorporeal şok dalga tedavisinin (ESWT) klinik ve sonografik sonuçlarını değerlendirmek ve karşılaştırmaktır.

Yöntemler: Kırk iki LE hastası rastgele iki gruba ayrıldı: ESWT grubu (n=21) ve sham-ESWT kontrol grubu (n=21). Her iki gruba da el bileği istirahat ateli, germe, el bileği ekstansörleri için güçlendirme egzersizleri ve buz uygulaması yapıldı. Grupların kavrama gücü Jamar el dinamometresi, ağrı, fonksiyonellik çeşitli testlerle ve ortak ekstansör tendon (CET) kalınlığı sonografik olarak tedaviden önce, tedaviden sonra ve tedaviden bir ay sonra kör bir denetçi tarafından ölçülmüştür.

Bulgular: Başlangıçta, gruplar arasında anlamlı bir fark yoktu. Her iki grupta ağrı basınç eşiği (PPT), kavrama gücü, görsel analog skalası (VAS), Hasta-değerlendirmeli Tenisçi Dirseği Değerlendirmesi (PRTEE) skorları başlangıç, tedavi sonrası ve tedaviden bir ay sonraki ölçümler arasında anlamlı farklılıklar gözlenmiştir ($p<0,05$). Ancak Kısa Form-12 (SF-12) fiziksel skorlar tedaviden sadece bir ay sonra anlamlı farklılık göstermiştir ($p<0,01$). SF-12 mental skor testinde her iki grupta da ölçümler arasında anlamlı fark bulunmamıştır. ESWT grubunda, CET kalınlığı tedavi sonrasında ve tedaviden bir ay sonra önemli ölçüde azalmıştır ($p<0,05$), ancak kontrol grubunda önemli bir fark gözlenmemiştir.

Sonuçlar: Hem ESWT hem de kontrol grupları ağrıda azalma ve işlevsellikte iyileşme göstermiştir. Ancak, ESWT grubu kontrol grubuna kıyasla ağrı azalması ve fonksiyonel iyileşme açısından istatistiksel olarak daha üstün sonuçlar sergilemiştir. Ek olarak, sonografik değerlendirme ESWT grubunda CET kalınlığında anlamlı bir azalma olduğunu ortaya koyarken, kontrol grubunda anlamlı bir değişiklik kaydedilmemiştir.

Anahtar kelimeler: Lateral epikondilit, ekstrakorporeal şok dalga tedavisi (ESWT), sonografik değerlendirme

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Presented in: Presented as an oral presentation at the 17th Congress of the European Forum for Research in Rehabilitation (EFRR) in Antalya/Türkiye on November 2-5, 2023.

Received: 17 March 2024
Accepted: 20 May 2024
Online First: 30 May 2024

Cite as: Murat S, Dogruoz Karatekin B, Zengin M. Clinical and Sonographic Evaluation of the Effectiveness of Extracorporeal Shock Wave Therapy in Patients with Lateral Epicondylitis. Medeni Med J 2024;39:109-116

INTRODUCTION

Lateral epicondylitis (LE), commonly known as tennis elbow, is a prevalent musculoskeletal condition characterized by pain and tenderness around the lateral epicondyle of the humerus[1].

Its incidence affects approximately 1-3% of the global population annually, with individuals aged 35 years being predominantly affected. It is also noteworthy that the prevalence is higher and the duration is longer in women than in men[2,3].

Although the exact cause of LE is often nonspecific, it is frequently associated with overuse of the elbow, particularly in the dominant arm and among tennis players, leading to repetitive micro-tears, degeneration, and tendinosis[4].

Reduced grip and upper extremity strength, as well as pain that travels from the lateral side of the elbow to the forearm and possibly the upper arm, are signs of LE. Pain is typically exacerbated by activities that involve contraction of the common extensor muscle mass, such as resisted dorsiflexion of the wrist[5].

The severity of pain can range from intermittent and mild to constant and severe, significantly impacting functional ability and performance in occupational and sport activities and even disrupting sleep patterns[6]. The duration of symptoms ranges from 6 months to 2 years, with a general tendency to be self-limiting, and approximately 70-90% of affected patients experience complete resolution within 1 year[7]. However, the overall discomfort and functional disability experienced during the 6-month to 2-year duration can be substantial[8]. Clinical and radiological evaluations are used in the diagnosis[9]. Tenderness with palpation on the lateral epicondyle, positive Cozen's test, and decrease in hand grip strength are important physical examination findings[5]. A significant relationship was also determined between clinical symptoms of LE and diagnostic ultrasonography (USG) findings. USG findings may reveal changes such as increased common extensor tendon (CET) thickness, focal hypoechogenicity, intratendinous calcification, and bone abnormalities[10]. It has been stated that clinical features in patients with chronic LE are associated with the pain threshold value and structural changes in USG[11]. However, in many intervention group studies, the correlation between maximum tendon thickness and clinical parameters, hand grip strength, and pain threshold value varied[3,12,13].

Various treatments have been used for LE[3,7,13,14], and conservative management recommended initially[14]. Some of the treatments available for this condition include physical therapy (such as rest, limited movement, modifying activities, using hot or cold compresses, electrotherapy, massage, and USG), splinting, injections directly into the affected area [such as corticosteroids or platelet-rich plasma (PRP)], oral or topical nonsteroidal anti-inflammatory drugs, and extracorporeal shock wave therapy (ESWT)[3,7,13-15]. Surgery is also considered in severe cases[15].

ESWT is a safe and noninvasive option, known to have minimal side effects like discomfort during treatment and minor bruising[15]. The mechanism of ESWT is not exactly understood, but it appears to involve mechanotransduction triggering cellular changes, increasing collagen synthesis, accelerating vascularization, which promote the healing process and reduce pain in musculoskeletal conditions[4,16]. ESWT has demonstrated efficacy in treating a wide range of musculoskeletal conditions, such as pseudoarthrosis, delayed fracture healing, bone marrow edema, early-stage osteonecrosis, insertional tendinopathies, calcifying tendonitis, tennis elbow, and wound healing issues[15].

There are many studies on the positive effects of radial ESWT (rESWT) on pain and functional status in LE[1,17,18]. However, studies investigating the effect of rESWT on ultrasonographically measured CET thickness in LE are insufficient and yield different results[3,19].

Therefore, the present study aimed to investigate the effects of ESWT on pain, pain-pressure threshold, functional status, quality of life, and ultrasonographically measured CET thickness in patients with LE.

MATERIALS and METHODS

Patients and Methods

Study Design

The present study is a prospective, randomized, and controlled study conducted in a single center. Patients diagnosed with LE who visited the Istanbul Medeniyet University Goztepe Training and Research Hospital between the years 2020 and 2021 were included in the study. This study was approved by the Istanbul Medeniyet University Goztepe Training and Research Hospital Clinical Research Ethics Committee (decision no: 2020/0657, date: 18.11.2020) (Clinical Trial registration number: NCT06342518). All participants willingly provided their signed consent to participate in this project. All medical inquiries adhered to the ethical guidelines set forth in the Declaration of Helsinki.

The participants between the ages of 18 and 60 who applied to the university's physical medicine and rehabilitation outpatient clinic with the complaint of elbow pain were assessed for the study. Those who met the criteria of experiencing pain and tenderness in the lateral epicondyle while extending their wrist and fingers against resistance for at least 3 months were included in the study.

Patients who were pregnant or have a coagulation disorder, cervical radiculopathy, peripheral neuropathy, peripheral vasculopathy in the upper extremity, complex regional pain syndrome, local infections, systemic inflammatory disease, fibromyalgia syndrome, arthritis (including rheumatoid arthritis, spondylarthritis, and crystal-induced arthropathies), malignancy, or those who have been treated with corticosteroids, PRP, or autologous blood injection, as well as those who have received physical therapy agents, undergone upper extremity surgical interventions, or had a history of direct trauma to the elbow or a history of fracture, were excluded from the study.

Forty-two patients who met the inclusion criteria were randomized into two groups using a computer-generated random number list: the ESWT group (n=21) and the sham-ESWT control group (n=21) (Figure 1). A wrist resting splint, wrist extensor strengthening and stretching exercises, and ice treatment were administered to both groups. Ensuring proper usage of the resting splint by the patient was confirmed during follow-up visits. The physician instructed the patients on stretching and strengthening exercises for wrist extensors, which they were asked to perform three times a day. Application of ice for 20 min every 3-4 hours during painful periods was recommended. During follow-up visit, patients confirmed their adherence to exercises and recommendations.

Baseline, post-treatment, and 1-month post-treatment assessments were conducted by a blinded researcher. Hand grip strength was measured using a Jamar hand dynamometer. Measurements were made while the patients were sitting in a chair with their arms supported, shoulder in adduction and neutral position, elbow in 90° flexion, forearm in neutral position, and wrist in 0-30° extension and 0-15° ulnar deviation position, and the average measurement was recorded. Pain severity was evaluated using the visual analog scale (VAS), which was scored from 0 (no pain) to 10 (extremely severe). Functionality was assessed using the Patient-rated Tennis Elbow Evaluation (PRTEE), quality of life was measured using the Short Form-12 (SF-12), deep muscular tissue sensitivity was measured using the pain pressure threshold (PPT), and the thickness of the CET was measured sonographically.

ESWT Protocol

The ESWT group received rESWT on the painful lateral epicondyle once per week for 3 sessions, with 2000 pulses at a frequency of 10 Hz. A gel was used at the interface, and the air pressure was set at 1.8 bar per session.

The sham-ESWT group also received sham-rESWT on the painful lateral epicondyle once per week for 3 sessions, but without actual contact of the applicator. To enhance the illusion of treatment, a gel was applied, and the device emitted a sound at every shock. Throughout the study, the patient, the physician responsible for the patient's assessment, and the physician conducting the USG evaluation remained unaware of the patient's assigned group.

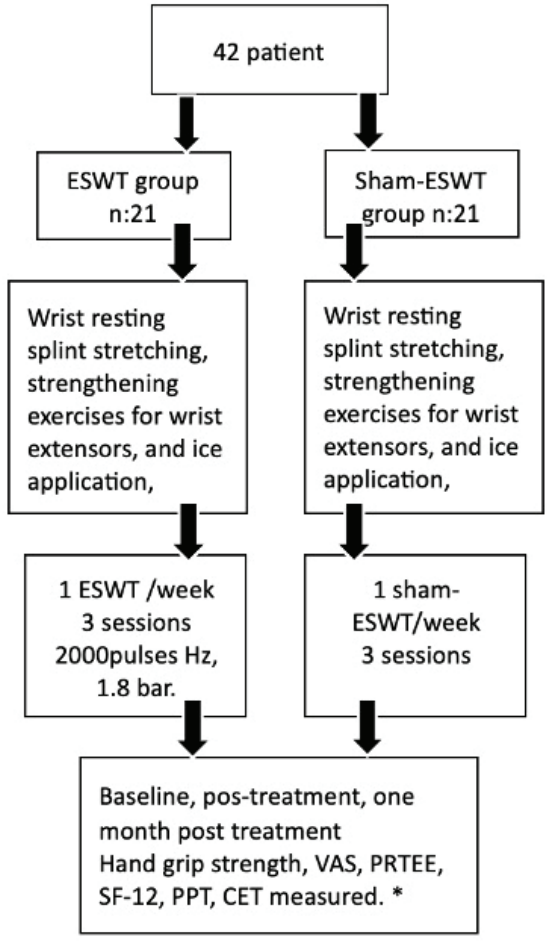

Figure 1. Flow diagram of the study.

VAS: Visual analog scale, PRTEE: Functionality was assessed using the Patient-rated Tennis Elbow Evaluation, SF-12: Quality of life was measured using the Short Form-12, PPT: Pain pressure threshold, CET: Common extensor tendon, ESWT: Extracorporeal shock wave therapy

Ultrasonographic Evaluation

The extensor digitorum, extensor carpi ulnaris, extensor digiti minimi, and extensor radialis brevis tendons join the anterior portion of the lateral epicondyle of the humerus to form the CET. Ultrasonographic examination of tendinosis in the CET typically reveals thickening of the tendon, focal hypoechoic areas, peritendinous fluid, linear intrasubstance tears, bone irregularities, calcifications, enteropathies, and diffuse tendon heterogeneity[20]. During USG for LE, the elbow is positioned at 90° of flexion and the wrist is in pronation. The USG probe is placed longitudinally on the radial surface of the elbow (Figure 2)[20]. The CET thickness is measured.

Statistical Analysis

Statistical analyses were performed using SPSS software version 25.0 (IBM Corp., Chicago, IL). Descriptive statistics are presented as mean ± standard deviation (range) for continuous variables, whereas frequency values (number of cases) are reported for categorical variables. The Mann-Whitney U test was used to evaluate differences between groups for continuous variables due to the non-normal distribution of the data. Within-group comparisons of continuous variables across different time periods were performed using the Wilcoxon signed-rank test. A significance level of $p<0.05$ was considered statistically significant.

Figure 2. Ultrasonographic measurement of common extensor tendon thickness.

RESULTS

This study included 42 patients diagnosed with chronic LE. Half of the patients received sham-ESWT (n=21) and the other half received ESWT treatment (n=21). The mean age of the patients was 41.40±8.30 years (27-56).

Baseline characteristics of patients in the ESWT and sham-ESWT groups were analyzed separately in Table 1. There were no statistically significant differences observed between the groups with respect to the variables analyzed.

Differences Between the Control Group and ESWT Group

The test scores of the two groups were obtained before treatment, after treatment, and 1 month after treatment.

There was no significant difference in baseline test scores between the control and ESWT groups. However,

Table 1. Baseline data prior to treatment.

	Control group* (n=21)	ESWT group* (n=21)	p-value
Age (years)	41.09±9.17	41.71±7.56	0.81
Gender (F/M)	15/6	12/9	0.34
Side (R/L)	15/6	10/11	0.12
Pain pressure threshold	10.42±5.91	13.57±8.34	0.16
Grip strength	42.23±18.97	54.38±24.57	0.08
Common extensor tendon thickness	5.90±0.94	5.55±1.19	0.30
SF-12 PCS	37.71±8.48	39.42±7.35	0.48
SF-12 MCS	48.80±11.57	49.68±9.59	0.24
VAS	6.71±1.34	7.04±1.43	0.44
PRTEE pain	26.28±7.57	28.42±8.56	0.39
PRTEE function	29.02±7.92	28.23±8.39	0.75
PRTEE total	55.30±14.99	56.66±15.66	0.77

*Mean ± standard deviation. SF-12 PCS: Short Form-12 physical scores, SF-12 MCS: Short Form-12 mental score, VAS: Visual analog scale, PRTEE: Patient-rated Tennis Elbow Evaluation, ESWT: Extracorporeal shock wave therapy

there was a significant difference between the groups, except for the SF-12 physical scores (SF-12 PCS) at the 6th week and 3rd month (Table 2).

While there was no significant difference between the groups in terms of SF-12 PCS score at the beginning and after the treatment, a significant difference was found between the two groups 1 month after the treatment ($p<0.01$) (Table 2).

Differences Between Groups at Baseline, Post-treatment, and 1 Month Post-treatment

Test results obtained at baseline, after treatment, and 1 month after treatment were compared to determine the effect of treatment in the control and ESWT groups.

A statistically significant difference was found between the measurements of PPT, grip strength, SF-12 PCS, VAS, PRTEE pain, PRTEE function, and PRTEE total tests at baseline, post-treatment, and 1 month after treatment in both groups (Table 3).

In the SF-12 mental score test, no statistically significant difference was found between the measurements at the beginning, after treatment, and 1 month after treatment in both groups (Table 3).

In the measurement of CET thickness, there was no statistically significant difference between the measurements at the beginning, after the treatment, and 1 month after the treatment in the control group, whereas a significant difference was found in the ESWT group (Table 3).

DISCUSSION

In this study, we investigated the clinical and ultrasonographic effects of rESWT in patients with LE. LE, commonly known as tennis elbow, is a painful condition that can significantly affect an individual's quality of life and functional capacity[4]. While various treatment modalities have been explored, the use of rESWT in the management of LE has shown promise[17].

This study demonstrated that rESWT has several advantages as a conservative treatment for LE. First, a significant increase in grip strength was observed in the rESWT group compared with the control group, which indicates an improvement in functional capacity. Additionally, the VAS scores for pain significantly decreased in the rESWT group, highlighting its efficacy in pain management. This aligns with the results of the systematic review and meta-analysis conducted by Yao et al.[1]. Their meta-analysis of pain evaluation, including 14 trials with

Table 2. Descriptive statistics and Mann-Whitney U test results.

	Group		Before treatment			After treatment			After 1st month		
		n	Median	IQR	p	Median	IQR	p	Median	IQR	p
PPT	Control	21	10.00	7.00	0.24	13.00	6.00	**<0.001**	14.00	7.50	**<0.001**
	ESWT	21	11.00	13.00		17.00	11.00		20.00	11.00	
Grip strength	Control	21	40.00	17.50	0.10	40.00	22.50	**<0.05**	40.00	22.50	**<0.01**
	ESWT	21	50.00	40.00		50.00	35.00		60.00	37.50	
CET thickness	Control	21	6.00	1.00	0.40	6.00	1.10	**<0.01**	6.00	1.15	**<0.01**
	ESWT	21	5.90	1.55		5.00	1.65		5.00	1.55	
SF-12 PCS	Control	21	40.25	13.36	0.40	40.00	14.84	0.07	40.00	11.75	**<0.01**
	ESWT	21	41.67	13.59		45.03	12.07		50.49	8.02	
SF-12 MCS	Control	21	50.85	19.29	0.21	46.60	18.78	**<0.01**	48.68	10.87	**<0.01**
	ESWT	21	51.78	14.17		51.00	8.42		51.68	7.66	
VAS	Control	21	7.00	2.50	0.43	6.00	2.00	**<0.001**	6.00	2.00	**<0.001**
	ESWT	21	7.00	2.00		3.00	2.50		3.00	2.50	
PRTEE pain	Control	21	24.00	12.50	0.43	24.00	9.50	**<0.05**	22.00	9.50	**<0.01**
	ESWT	21	27.00	12.00		17.00	8.00		14.00	10.00	
PRTEE function	Control	21	32.00	14.75	0.68	29.00	13.50	**<0.01**	29.00	14.00	**<0.001**
	ESWT	21	32.00	12.00		18.50	17.00		16.00	16.00	
PRTEE total	Control	21	55.00	25.75	0.82	55.00	19.50	**<0.01**	52.00	20.00	**<0.001**
	ESWT	21	60.00	25.50		33.50	25.00		27.00	24.00	

PPT: Pain pressure threshold, CET: Common extensor tendon, SF-12 PCS: Short Form-12 physical scores, SF-12 MCS: Short Form-12 mental score, VAS: Visual analog scale, PRTEE: Patient-rated Tennis Elbow Evaluation, IQR: Interquartile range, ESWT: Extracorporeal shock wave therapy

Table 3. Descriptive statistics and Wilcoxon signed-rank test and Friedman test results.

	Measurement	n	Control group			n	ESWT group		
			Median	IQR	p		Median	IQR	p
PPT	Before treatment	21	10.00[a]	7.00	**<0.001**	21	11.00[a]	13.00	**<0.001**
	After treatment	21	13.00	6.00		21	17.00[b]	11.00	
	After 1st month	21	14.00[c]	7.50		21	20.00[c]	11.00	
Grip strength	Before treatment	21	40.00[a]	17.50	**<0.01**	21	50.00[a]	40.00	**<0.001**
	After treatment	21	40.00	22.50		21	50.00[b]	35.00	
	After 1st month	21	40.00	22.50		21	60.00[c]	37.50	
CET thickness	Before treatment	21	6.00	1.00	0.58	21	5.90[a]	1.55	**<0.001**
	After treatment	21	6.00	1.10		21	5.00	1.65	
	After 1st month	21	6.00	1.15		21	5.00[c]	1.55	
SF-12 PCS	Before treatment	21	40.25[a]	13.36	**<0.01**	21	41.67[a]	13.59	**<0.001**
	After treatment	21	40.00	14.84		21	45.03[b]	12.07	
	After 1st month	21	40.00[c]	11.75		21	50.49[c]	8.02	
SF-12 MCS	Before treatment	21	50.85	19.29	1.00	21	51.78	14.17	0.11
	After treatment	21	46.60	18.78		21	51.00	8.42	
	After 1st month	21	48.68	10.87		21	51.68	7.66	
VAS	Before treatment	21	7.00[a]	2.50	**<0.001**	21	7.00[a]	2.00	**<0.001**
	After treatment	21	6.00	2.00		21	3.00[b]	2.50	
	After 1st month	21	6.00[c]	2.00		21	3.00[c]	2.50	
PRTEE pain	Before treatment	21	24.00[a]	12.50	**<.001**	21	27.00[a]	12.00	**<0.001**
	After treatment	21	24.00	9.50		21	77.00[b]	8.00	
	After 1st month	21	22.00[c]	9.50		21	14.00[c]	10.00	
PRTEE function	Before treatment	21	32.00[a]	14.75	**<.001**	21	32.00[a]	12.00	**<0.001**
	After treatment	21	29.00	13.50		21	18.50[b]	17.00	
	After 1st month	21	29.00[c]	14.00		21	16.00[c]	16.00	
PRTEE total	Before treatment	21	55.00[a]	25.75	**<.001**	21	60.00[a]	25.50	**<0.001**
	After treatment	21	55.00[b]	19.50		21	33.50[b]	25.00	
	After 1st month	21	52.00[c]	20.00		21	27.00[c]	24.00	

[a]Before and after treatment (p<0.05), [b]After treatment and 1 month after treatment (p<0.05), [c]Before treatment and 1 month after treatment (p<0.05). PPT: Pain pressure threshold, CET: Common extensor tendon, SF-12 PCS: Short Form-12 physical scores, SF-12 MCS: Short Form-12 mental score, VAS: Visual analog scale, PRTEE: Patient-rated Tennis Elbow Evaluation, IQR: Interquartile range, ESWT: Extracorporeal shock wave therapy

950 patients, revealed significantly lower VAS scores in the ESWT group than in the other therapies. Additionally, the meta-analysis of grip strength, encompassing eight articles with 458 patients, demonstrated a significant increase in grip strength among patients receiving ESWT. Overall, their pooled results suggest that ESWT leads to better long-term grip strength improvement and faster pain relief. when compared to alternative therapies[1].In a study by Özmen et al.[19] on 40 patients diagnosed with LE, they divided the patients into three groups. Clinical and sonographic comparisons were made between the effects of kinesio taping, ESWT, and ultrasound therapy. While pain significantly decreased in all groups, grip strength only increased in the kinesio taping group. PRTEE scores significantly decreased in all groups by the 8th week. CET thickness significantly decreased only in the ESWT group. Although there was no superiority among the groups, the significant reduction in pain and decrease in CET thickness in LE with ESWT are consistent with our study results[19].Utilization of USG findings as an effective tool for assessing outcomes was also aimed in our study. The advancement of technology has magnified the significance of incorporating radiological images into the diagnostic process, and the diagnostic validity of musculoskeletal USG in LE has been a subject of extensive research[9,21]. In this context, a review conducted by Dones et al.[21], which included a meta-analysis of 15 studies, stands out. The analysis revealed that gray-scale

USG is advantageous for objectively diagnosing LE. In this analysis, various factors such as hypoechogenicity, calcifications, neovascularity, thickness, enthesopathy, cortical irregularities, cortical spurs, bone changes, cortical irregularities, partial tears, and full tears were also individually assessed for statistical analysis. Among the various changes examined, hypoechogenicity emerged as the key diagnostic finding with the highest sensitivity and specificity, whereas significant differences in thickness were also observed. According to the meta-analysis, the sensitivity of thickness was 0.51 (0.47-0.55) and the specificity was 0.80 (0.75-0.84)[21]. Although its sensitivity may not be sufficiently high for exclusive diagnostic purposes, its remarkable specificity is notable. Furthermore, our study detected a significant reduction in tendon thickness following treatment. This aligns with the results of the meta-analysis, and our research provides promising evidence for the use of tendon thickness as a radiological indicator of recovery in LE. This raises hope for future assessments of treatment effectiveness.

However, it is essential to acknowledge the limitations of this study, including the relatively small sample size and short follow-up period. Future research with larger cohorts and longer-term follow-up is needed to further explore the efficacy and safety of rESWT in treating LE. Additionally, more extensive investigations should be conducted to establish a stronger correlation between USG findings and clinical scores, potentially providing valuable information for predicting disease prognosis and treatment outcomes.

CONCLUSION

In conclusion, this study suggests that rESWT is a promising treatment modality for LE, offering benefits in terms of grip strength improvement and pain reduction. The use of USG as a diagnostic tool in LE assessment and treatment monitoring has been reinforced by the findings of previous studies. It provides valuable insights for further research to expand the understanding of rESWT's role in LE management and the potential implications of USG findings on disease prognosis and healing time.

Acknowledgement: We would like to give our special thanks to Prof. Dr. Afitap Icagasioglu for her support, and supervision.

Ethics

Ethics Committee Approval: This study was approved by the Istanbul Medeniyet University Goztepe Training and Research Hospital Clinical Research Ethics Committee (decision no: 2020/0657, date: 18.11.2020).

Informed Consent: All participants willingly provided their signed consent to participate in this project.

Author Contributions

Surgical and Medical Practices: S.M., B.D.K., M.Z., Concept: S.M., B.D.K., M.Z., Design: S.M., B.D.K., M.Z., Data Collection and/or Processing: S.M., B.D.K., M.Z., Analysis and/or Interpretation: S.M., B.D.K., M.Z., Literature Search: S.M., B.D.K., M.Z., Writing: S.M., B.D.K., M.Z.

Conflict of Interest: The authors have no conflict of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

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