

Comparison of the effectiveness of radial extracorporeal shock wave therapy and supervised exercises with neuromuscular inhibition technique in lateral epicondylitis: A randomized-controlled trial

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ABSTRACT

Objectives: The aim of this study was to evaluate and compare the effects of radial extracorporeal shock wave therapy (rESWT) and supervised exercises with neuromuscular inhibition (NMI) technique in improving pain, function, and grip strength in the treatment of patients with lateral epicondylitis (LE).

Patients and methods: A total of 50 patients with LE (11 males, 30 females; median age: 46 years; range, 23 to 57 years) whose symptoms persisted for at least three months between February 2015 and August 2015 were included in the prospective, randomized-controlled, clinical study. The patients were divided into two groups as the rESWT group (n=25) receiving a total of three rESWT sessions (once per week with 1.8 bar pneumatic pressure, 10 Hz frequency, and with 2,000 pulses) and the exercise group (n=25) receiving supervised exercises with NMI (three times per week for three weeks). Pain and function were evaluated using Visual Analog Scale, the total Patient-Rated Tennis Elbow Evaluation, the Roles and Maudsley score, while the grip strength was evaluated using a hand dynamometer at one and three months after treatment compared to baseline.

Results: A significant improvement was observed in all outcome criteria at one and three months after treatment, compared to baseline, in both the rESWT and exercise groups (p<0.05). There was no significant difference in terms of the changes in the outcome criteria between the groups (p>0.05).

Conclusion: The rESWT seems to provide no significantly superior benefit than supervised exercises with NMI at least until the three months in the treatment of LE.

Keywords: Extracorporeal shockwave therapy, pain, physical therapy modalities, tennis elbow.

Lateral epicondylitis (LE), which is an elbow tendinopathy and frequently referred to as tennis elbow, is a common musculoskeletal system disorder. The prevalence in the adult population is estimated to be approximately 1 to 3%.^[1] Epidemiological studies have shown that the prevalence increases up to 13.5% among adults of working age.^[2] Repetitive and high load movements in various jobs, and in sports have a strong contribution to LE, which is defined as an overuse injury.^[3] The pathophysiology of LE includes

non-inflammatory processes of mucoid degeneration, resulting in neovascularization, scarring, and microtearing in the joint extensor tendon of the elbow, also known as angiofibroblastic hyperplasia or tendinosis.^[4]

Treatment options for LE range from pharmacological treatments, injection therapies, splinting, rehabilitation approaches, to surgery. The efficacy of short-term conservative treatments with

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non-steroidal anti-inflammatory drugs, corticosteroid injections, laser therapy, therapeutic ultrasound (US), and exercise have been shown to reduce pain and function loss associated with LE.^[5-8] Despite comprehensive researches on the optimal treatment option in the literature, no precise evidence has yet been provided.

Owing to its positive outcomes, extracorporeal shock wave therapy (ESWT) has recently been used in the treatment of musculoskeletal system diseases.^[9-11] High-energy sound waves with transient pressure oscillations, which are described as extracorporeal shock waves, release the angiogenetic growth and proliferation factors through mechanotransduction and increase tissue regeneration by inducing an amelioration response with neovascularization. In addition, ESWT provides an anti-inflammatory effect by reducing the expression of inflammatory cytokines and an analgesic effect by direct suppression of the nociceptor activity through hyperstimulation analgesia.^[12] Buchbinder et al.^[13] demonstrated that ESWT was not superior to placebo on pain and function in LE; however, Rompe and Maffulli^[14] reported that positive effects of ESWT might be detected in chronic refractory cases.

The ESWT and exercise have beneficial effects on the management of tendinopathies thanks to their various mechanisms showing the therapeutic efficacy. In the present study, we aimed to compare the efficacy of radial ESWT (rESWT) and supervised exercises with neuromuscular inhibition (NMI) technique on pain, function, and grip strength in patients with chronic LE.

PATIENTS AND METHODS

This prospective, randomized-controlled, clinical study was conducted at Istanbul University, Istanbul Faculty of Medicine, Department of Physical Medicine and Rehabilitation between February 2015 and August 2015. The patients with LE were randomly selected to receive either rESWT or supervised exercises with NMI. Prior to study, all patients were informed about the nature of the study and a written informed consent was obtained. The study protocol was approved by the Istanbul University, Istanbul Faculty of Medicine Ethics Committee (IRB study protocol: 2015/369). The study was conducted in accordance with the principles of the Declaration of Helsinki. This study is registered at ClinicalTrials.gov (NCT03834090).

A total of 50 patients with LE (11 males, 30 females; median age: 46 years; range, 23 to 57 years) whose

symptoms persisted for at least three months were included in the study. The patients were divided into two groups as the rESWT group (n=25) receiving a total of three rESWT sessions (once per week with 1.8 bar pneumatic pressure, 10 Hz frequency, and with 2,000 pulses) and the exercise group (n=25) receiving supervised exercises with NMI (three times per week for three weeks). Randomization was performed with a 1:1 allocation ratio using a computer program. After randomization, rESWT was performed by a single researcher and supervised exercises with NMI by a single physiotherapist. All the evaluation (baseline, at one and three months after treatment), and data collection were completed by another researcher who was blinded to the randomization and group allocation and to the procedures conducted in both groups.

The diagnosis of LE was made based on the clinical examination findings and confirmed with the Southampton Diagnostic Criteria (i.e., the presence of epicondyle pain, and epicondyle pain and tenderness on resisted extension of the wrist).^[15] Patients with symptoms lasting longer than three months, with average pain in the previous week detected as ≥ 3 on a 10-cm Visual Analog Scale (VAS), and those aged over 18 years were included in the study. Exclusion criteria were as follows: pain in the proximal part of the affected extremity (e.g. shoulder pain, neck pain); abnormal neurogenic symptoms (e.g. radicular pain, numbness) on the affected extremity; presence of posterior interosseous nerve entrapment; congenital or acquired upper extremity deformities that can affect the grip strength; systemic musculoskeletal system or neurological disorders; systemic rheumatological disease or systemic infection; presence of malignancy, coagulation disorders, and anticoagulant use; inserted cardiac pacemaker; history of surgical treatment on the elbow of the affected extremity; and pregnancy. Patients who were administered other treatments such as physical therapy or steroid injections within the past three months were also excluded from the study.

The use of analgesics against epicondylitis pain was restricted, except for cold application and paracetamol. The patients were not allowed to do exercise or sports activities and they were informed about the importance of the discontinuation of activities that may worsen the epicondylitis symptoms. The participation of patients to the treatment sessions was recorded by the physiotherapist.

rESWT

The rESWT was administered once per week for three weeks using a ShockMaster 500 device

(GymnaUniphy NV, Bilzen, Belgium) with 1.8 bar pneumatic pressure, 10 Hz frequency, with 2,000 pulses. The affected upper extremity of the patient was placed on a platform with 90-degree elbow flexion, and the forearm was kept in a neutral position. Radial shock waves were transmitted to the epicondylar region with the maximum pain/tenderness that was identified with patients' reaction with small circular movements using a standard 15-mm applicator with an adequate amount of contact gel.

Supervised exercises with NMI technique

A program including NMI technique (post-isometric relaxation) and progressive resistance exercise on the wrist extensors was performed for patients three times weekly for three weeks. About 10 to 20 repetitive passive stretching exercises were performed for 30 sec after a 10-sec isometric contraction to the wrist extensors in each session before the resistance exercises by the physiotherapist. Following the pronation and flexion of the wrist, the slow extension was performed at the elbow, until reaching the maximum extension position. An eccentric wrist extension exercise was performed

using elastic resistance bands with 10 to 15 repeats in three to five sets, and with 1-min resting between each set. Progressive resistance exercise was individualized in accordance with patients' capacity without stimulating pain, and by the regulation of the optimal volume and load. In addition, patients in each group were asked to perform wrist extensor stretching and eccentric strengthening exercises as daily home exercises, until the evaluation at one month after treatment.

Outcome measurements

The self-evaluation of pain severity during rest and activity in the previous week was calculated using a 10-cm VAS scale, where 0 in the left corner of the scale represented no pain and 10 in the right corner represented the worst imaginable pain.

The Patient-Rated Tennis Elbow Evaluation (PRTEE) is a specific questionnaire designed for the evaluation of the disease-specific pain and function/disability in LE. It consists of a pain scale with five items questioning pain during rest and specific activities (0 represents no pain and 10 represents the worst

TABLE 1
Baseline demographic and clinical characteristics of patients

Characteristics	rESWT group (n=22)				Exercise group (n=19)				p
	n	%	Median	Min-Max	n	%	Median	Min-Max	
Age (year)			49.0	23-57			45.0	28-55	0.773
Sex									0.945
Female	16	72.7			14	73.7			
Male	6	27.3			5	26.3			
Weight (kg)			70.0	54-100			72.0	56-88	0.977
Height (cm)			165.0	147-183			165.0	150-181	0.906
Body mass index (kg/m ²)			26.0	19.8-35.4			25.1	20-34.1	0.937
Affected extremity									0.902
Right	12	54.5			10	52.6			
Left	10	45.5			9	47.4			
Duration of symptoms									0.050
3-month - 6-month	11	50.0			7	36.8			
6-month - 1-year	8	36.4			3	15.8			
>1 year	3	13.6			9	47.4			
Receiving previous treatment	22	100			16	84.2			0.182
Oral and/or topical NSAIDs	11	50.0			4	21.1			
Cold application	2	9.1			1	5.3			
Bracing	2	9.1			4	21.1			
Corticosteroid injection	0	0.0			3	15.8			
Other treatments	7	31.8			4	21.1			

rESWT: Radial extracorporeal shock wave therapy; NSAIDs: Non-steroidal anti-inflammatory drugs; P values for continuous variables were calculated using Mann-Whitney U test; P values for categorical data were calculated using Pearson chi-squared test or Fisher exact test.

imaginable pain), and a function/disability scale with 10 items evaluating difficulties experienced during specific and daily activities (0 represents no difficulty and 10 represents the highest difficulty). The scores were calculated separately and as the total PRTEE score, where 0 represented the best score, and 100 represented the worst score.

The Roles and Maudsley (RM) score was used to evaluate pain and activity limitation as classified in four categories: 1 point = excellent, 2 points = good, 3 points = fair, and 4 points = poor.

The grip strength of the affected upper extremity was calculated using a Jamar® hydraulic

hand dynamometer (Sammons Preston Rolyan, Bolingbrook, IL, USA). The patients were asked to perform as tolerable maximum grip strength to the hand dynamometer while sitting on a chair with 90-degree elbow flexion, the shoulder in the adduction position, wrist in slight extension and ulnar deviation, and the forearm in the neutral position. Three consecutive measurements were performed with 30-sec intervals, and the average values of these calculations (kg) were included in the data analysis.

Statistical analysis

Study power and sample size calculation were performed using the G*Power version 3.1.9.4 software

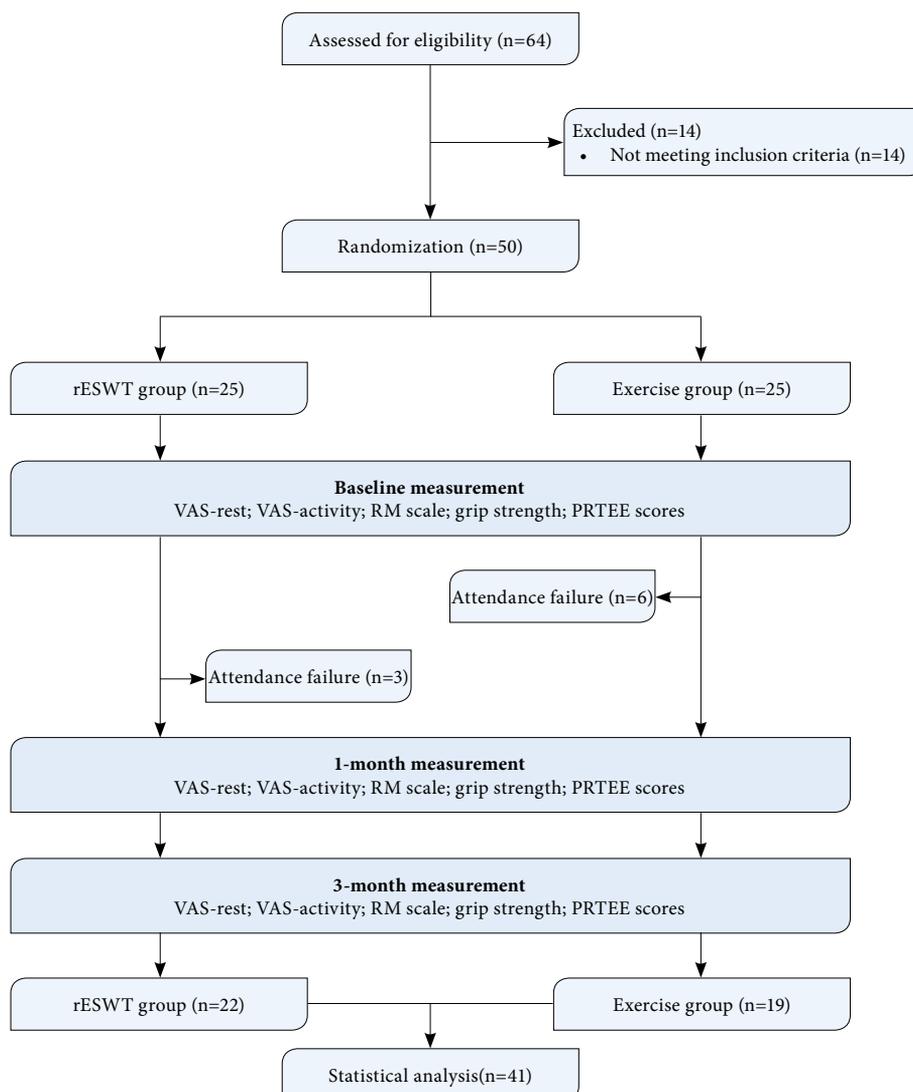


Figure 1. Study flow chart.

rESWT: Radial extracorporeal shock wave therapy; VAS: Visual Analog Scale; RM: Roles and Maudsley; PRTEE: Patient-rated tennis elbow evaluation.

TABLE 2

Intra- and inter-group changes of pain, function, and grip strength in the rESWT and exercise groups

Outcome measures	Groups	Baseline				1-month				3-month				Within-group comparisons		Between-group comparisons	
		Median	Min-Max	Median	Min-Max	Median	Min-Max	Median	Min-Max	Baseline vs. 1-month	Baseline vs. 3-month	p	Baseline vs. 1-month	Baseline vs. 3-month	p	p	
VAS-test	rESWT	5.0	0.0-9.0	3.5	0.0-9.0	2.0	0.0-8.0	0.001	0.001	<0.001	<0.001	0.202	0.411				
	Exercise	4.0	3.0-8.0	3.0	0.0-6.0	2.0	0.0-6.0	<0.001	<0.001	<0.001	<0.001	0.058	0.607				
VAS-activity	rESWT	8.0	3.0-10.0	6.0	1.0-10.0	3.5	0.0-9.0	<0.001	<0.001	<0.001	<0.001	0.061	0.854				
	Exercise	8.0	4.0-10.0	4.0	2.0-10.0	3.0	0.0-10.0	<0.001	<0.001	<0.001	<0.001	0.895	0.401				
RM score	rESWT	3.0	2.0-4.0	3.0	2.0-4.0	2.0	1.0-4.0	0.020	0.001	0.001	0.001	0.061	0.854				
	Exercise	3.0	2.0-4.0	2.0	2.0-4.0	2.0	1.0-4.0	0.001	0.001	0.001	0.001	0.061	0.854				
Grip strength	rESWT	8.0	0.0-35.0	10.5	2.0-40.0	12.0	2.0-42.0	0.005	0.002	0.002	0.002	0.895	0.401				
	Exercise	10.0	0.0-32.0	14.0	7.0-33.0	12.0	8.0-38.0	0.006	0.001	0.001	0.001	0.895	0.401				
PRTEE-pain rest	rESWT	5.0	0.0-10.0	2.0	0.0-10.0	2.0	0.0-10.0	0.008	0.002	0.002	0.002	0.291	0.781				
	Exercise	3.0	0.0-8.0	0.0	0.0-6.0	1.0	0.0-9.0	0.001	0.031	0.031	0.031	0.291	0.781				
PRTEE-pain activity	rESWT	8.5	3.0-10.0	5.0	1.0-10.0	4.0	0.0-10.0	0.001	0.001	<0.001	<0.001	0.534	0.741				
	Exercise	8.0	4.0-10.0	5.0	0.0-10.0	5.0	0.0-10.0	<0.001	<0.001	<0.001	<0.001	0.534	0.741				
PRTEE-pain total	rESWT	33.0	9.0-50.0	19.0	3.0-43.0	15.5	0.0-50.0	<0.001	<0.001	<0.001	<0.001	0.834	0.675				
	Exercise	28.0	14.0-41.0	16.0	3.0-41.0	15.0	0.0-41.0	<0.001	<0.001	<0.001	<0.001	0.834	0.675				
PRTEE-specific activity	rESWT	35.0	10.0-59.0	21.5	2.0-58.0	15.5	0.0-59.0	<0.001	<0.001	<0.001	<0.001	0.713	0.924				
	Exercise	34.5	15.0-51.0	18.0	1.0-52.0	17.0	0.0-53.0	0.001	0.001	<0.001	<0.001	0.713	0.924				
PRTEE-usual activity	rESWT	23.5	5.0-39.0	14.0	2.0-37.0	11.5	0.0-37.0	<0.001	<0.001	<0.001	<0.001	0.937	0.990				
	Exercise	19.0	5.0-34.0	11.0	2.0-28.0	8.0	0.0-26.0	<0.001	<0.001	<0.001	<0.001	0.937	0.990				
PRTEE-function total	rESWT	29.2	7.5-49.0	16.7	2.0-47.5	13.5	0.0-48.0	<0.001	<0.001	<0.001	<0.001	0.804	0.917				
	Exercise	25.0	13.0-41.0	13.5	2.0-39.0	13.5	0.0-39.5	0.001	0.001	<0.001	<0.001	0.804	0.917				
PRTEE total	rESWT	66.5	16.5-98.5	37.0	5.0-88.5	27.2	0.0-98.0	<0.001	<0.001	<0.001	<0.001	0.875	0.814				
	Exercise	55.0	32.0-77.0	32.0	5.0-80.0	34.5	0.0-80.5	<0.001	<0.001	<0.001	<0.001	0.875	0.814				

rESWT: Radial extracorporeal shock wave therapy; VAS: Visual Analog Scale; RM: Roles and Maudsley; PRTEE: Patient-Rated Tennis Elbow Evaluation; P: values for within-group comparisons were calculated using Wilcoxon signed-rank test; P values for between-group comparisons were calculated using Mann-Whitney U test.

(Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). Based on a previous study by Sarkar et al.^[16] in which the effect size was 1.05 for the differences of VAS scores with an alpha =0.05 and power =0.90, the projected total sample size needed was estimated to be 40 with an anticipated 20% dropout rate throughout the study period, and approximately 25 participants per treatment group were needed.

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in median (min-max) or number and frequency. The Kolmogorov-Smirnov test was used to analyze the normal distribution of quantitative variables. The Pearson chi-square test was carried out to analyze qualitative independent data, while Fisher's exact test was used when the test conditions could not be provided. The Wilcoxon signed-rank test was performed in the comparison of intragroup differences in the measurement intervals of the outcome criteria. Comparisons between the rESWT and exercise groups were performed using the Mann-Whitney U test. A *p* value of <0.05 was considered statistically significant.

RESULTS

Baseline demographic and clinical characteristics of patients are summarized in Table 1. A total of 41 patients (rESWT, n=22; exercise, n=19) completed the study. Nine patients were excluded from the final analysis due to irregular attendance (Figure 1). Intention-to-treat analysis was not performed, as the patients with irregular attendance were not included in the statistical analysis. While there was only a statistically significant difference in the duration of the disease between the groups, there was no statistically significant difference in terms of other clinical features and all outcome criteria at baseline.

There was a statistically significant improvement in all outcomes (VAS, RM scale, and PRTEE, grip strength) at one and three months in both the rESWT and exercise groups ($p<0.05$) (Table 2, Figure 2, 3). However, no significant difference was found in terms of the changes in any of the variables at any time points between the rESWT and exercise groups ($p>0.05$) (Table 2, Figure 2, 3). An improvement higher than the minimal clinically important difference (MCID)^[17] of 11 points for PRTEE total score was detected in patients in the rESWT

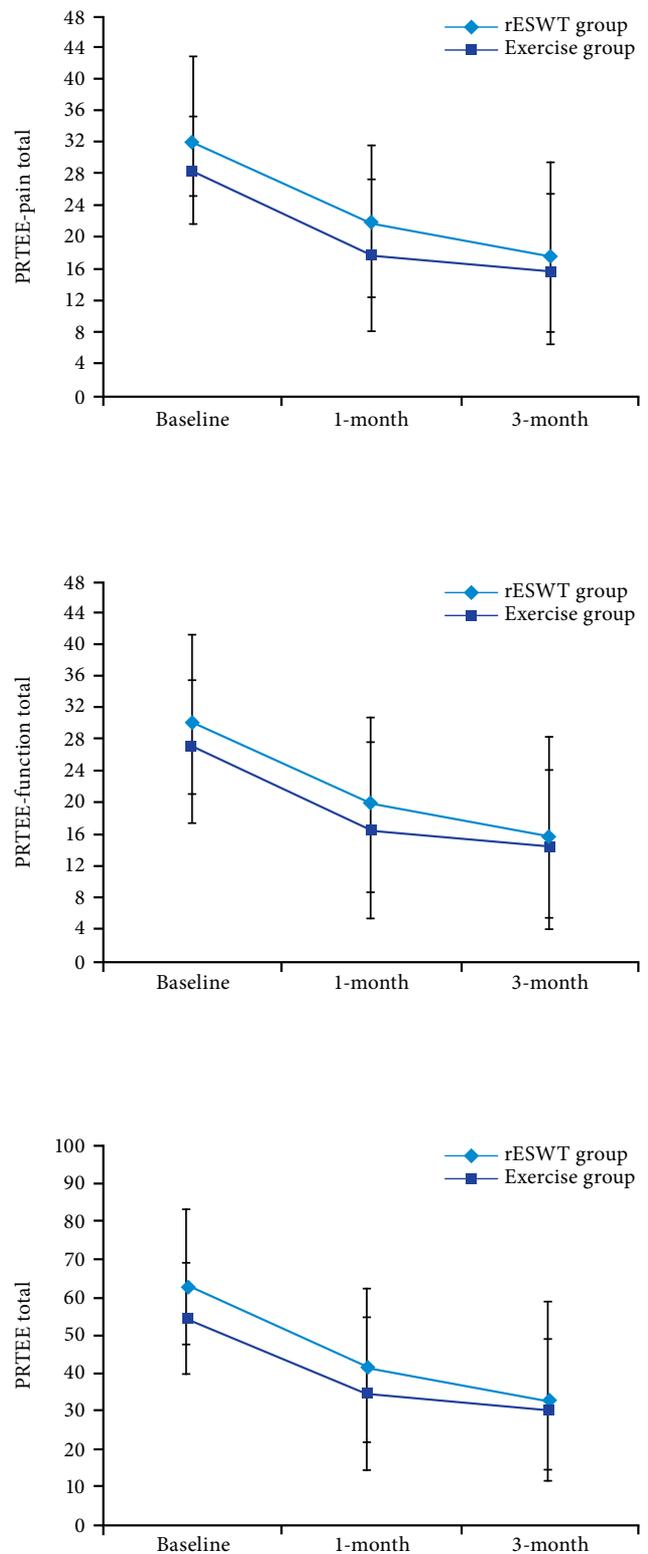


Figure 2. Changes in mean values with standard deviations for PRTEE-pain total, PRTEE-function total, and PRTEE total scores over time in each group.

PRTEE: Patient-Rated Tennis Elbow Evaluation; rESWT: Radial extracorporeal shock wave therapy.

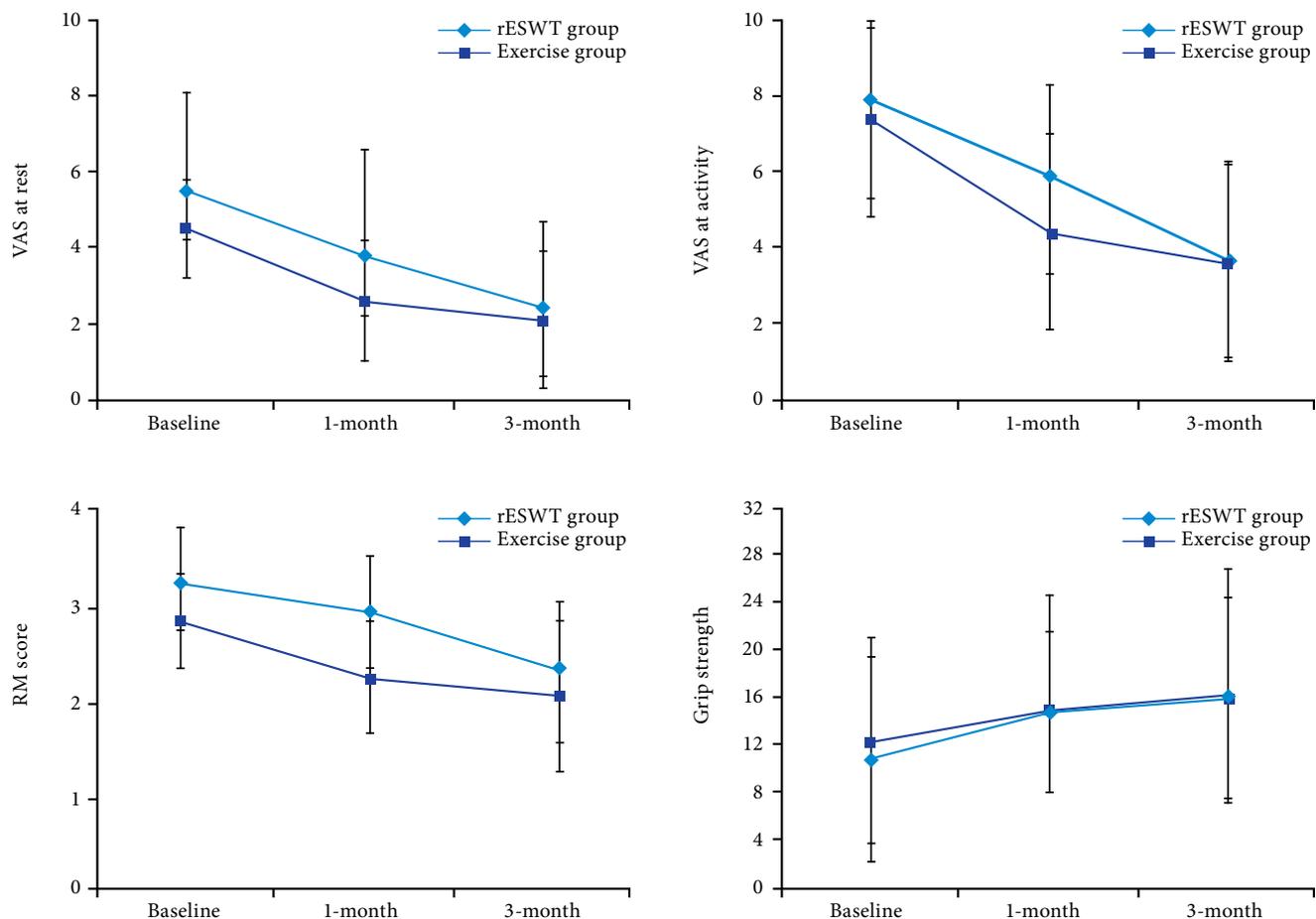


Figure 3. Changes in mean values with standard deviations for VAS at rest and activity, RM scores, and grip strength over time in each group.

rESWT: Radial extracorporeal shock wave therapy; VAS: Visual Analog Scale; RM: Roles and Maudsley.

group (-20.4 and -29.1, respectively) and exercise group at one and three months after the treatment (-19.9 and -24.1, respectively).

DISCUSSION

The present study is the first to compare the effects of rESWT and supervised exercises with NMI in the treatment of LE. The results of the study showed a statistically significant difference in all criteria at one and three months, compared to baseline values in both groups, and the within-group differences in PRTEE were greater than the 11-point MCID in the rESWT and exercise groups at one and three months (-20.4 and -29.1; -19.9 and -24.1, respectively). However, no significantly superior effects of rESWT to supervised exercises with NMI were observed in decreasing pain, and improving function and grip strength in the management of LE.

The results of our study are consistent with a systematic review showing that focused ESWT (fESWT) had no positive effects on LE, compared to placebo.^[13] Also, Capan et al.^[18] demonstrated similar improvements in pain and function in both active rESWT and sham rESWT groups in their randomized-controlled study in which they used the same device (ShockMaster 500) and the same treatment protocol as in our study (once per week for three weeks, with 1.8 bar pneumatic pressure, 10 Hz frequency, and 2,000 pulses). In addition, some other studies have shown that ESWT is not better or superior over physical therapy (combination of hot pack, US and friction massage), corticosteroid or autologous blood injection or percutaneous tenotomy.^[19-21] According to all these results and our findings, comparative studies of ESWT in patients with LE demonstrated the non-inferiority of ESWT with other treatments or sham treatments.

In their systematic review, Rompe and Maffuli^[14] recommended the use of ESWT in chronic refractory LE which was unresponsive to previous treatments. The ESWT seems to be the most appropriate method in the chronic phase, as it increases vascularization in the bone-tendon junction and tissue regeneration in the degenerative tendon. Although the study of Rompe et al.^[22] showed that ESWT had no effect in the early stage of plantar fasciopathy, which supported the study of Rompe and Maffuli,^[14] Chung et al.^[23] investigated the long-term effects of ESWT in LE and showed that ESWT was not more effective in patients with symptoms for longer than 16 weeks than symptoms lasting less than 16 weeks. Similarly, Koksall et al.^[24] found ESWT to be equally effective in their randomized-controlled, comparative study of ESWT in acute and chronic LE. It appears that ESWT may be useful in acute LE patients to relieve pain through hyperstimulation analgesia mechanism. Although researchers in a recent systematic review presented evidence that both fESWT and rESWT were effective in the treatment of tendinopathies, the efficacy of fESWT in the treatment of LE is controversial.^[11] It may be inappropriate to compare the results of fESWT and rESWT studies, as the treatment parameters (pulse counts, pressure, and frequency), and frequency of the treatments were heterogeneous, there were significant differences in the physical features of focus and radial shock waves, and the efficacy of the association of tendinopathies with different clinical physical features were unclear.^[25] Waves do not concentrate on a specific region in rESWT; instead the treatment region enlarges with dissemination to neighboring tissue, which may be suggested to be more beneficial for superficial injuries such as tendinopathies.^[25]

Spacca et al.^[26] showed improvements in the VAS scores, and the increase in the Disabilities of the Arm, Shoulder and Hand (DASH) scores and grip strength were statistically significant after the treatment and at six months of follow-up in their randomized-controlled study, which included 62 patients with chronic refractory LE in the rESWT treatment group (once weekly for four weeks, total of 2,000 pulses) versus the less active rESWT treatment group (once weekly for four weeks, total of 20 pulses). The results of the study of Spacca et al.^[26] are, however, inconsistent with our findings, which may be associated with the different number of sessions applied (four sessions), different pneumatic pressures (1.2 bar, and 1 bar, respectively), and different frequencies used (4 and 10 Hz, respectively).

In addition, this discrepancy can be attributed to the placebo rESWT application in the control group, and with the follow-up of treatment results until six months. In another randomized-controlled study, Yang et al.^[27] compared a group of patients receiving rESWT (once weekly for three weeks, at the maximum tolerable pressure of the patients, 10 Hz frequency with 2,000 pulses), and physical therapy (ultrasonic diathermy, transcutaneous electrical nerve stimulation, static stretching exercise, and transverse friction massage three times weekly) with the control group receiving sham rESWT (0.1 bar pressure, 10 Hz frequency with 2,000 pulses), and a physical therapy group consisting of 30 patients with LE. The decrease of pain was more significant in the study group at Week 24, and a greater maximum grip strength was detected at Weeks 12 and 24, compared to the control group; however, no significant difference was found in the DASH scores. The significant changes may be associated with the use of higher pneumatic pressure of radial shock waves (3.10 ± 0.30 bars), compared to the pneumatic pressure in our study (1.8 bar). However, the dose-associated effects of radial shock waves must be investigated in future clinical studies. Recent retrospective studies showed that individualized rESWT protocols resulted in higher success rates and less recurrence.^[28,29]

In their recent systematic review, Cullinane et al.^[8] showed that eccentric exercise programs alone or in addition to other treatments in the treatment of LE resulted in decreased pain, better function, and increased grip strength. Also, Stasinopoulos et al.^[30] found that supervised exercise program was superior to the home-based exercise program in reducing pain and improving function in patients with LE. Researchers in a comparison study of rESWT and eight-week specific stretching program demonstrated that patients with plantar fasciopathy were dissatisfied with rESWT as a primary therapeutic treatment method.^[22] Research in this area is still limited; however, the combined use of rESWT with exercise programs may result in better outcomes with a synergistic effect.^[31] This is also supported by the findings of the study by Sarkar et al.^[16] showing a significantly better improvement on pain and function with combined ESWT and supervised exercise than only exercise in patients with LE.

Nonetheless, there are some limitations to this study. First, the long-term effects were unable to be

evaluated, as the patients were followed in the short term. Second, the patients were not blinded to the treatment, as the exercise group received no sham rESWT. Finally, we were unable to measure the patient adherence and compliance to the home exercises, and we have no data to identify whether some results were correspondingly affected. On the other hand, the main strength of the present study is that it is the first to investigate the effectiveness of the rESWT and supervised exercises with NMI in patients with LE. Another strength is that the exercise sessions were supervised by a physiotherapist, which minimized variability in the exercise sessions.

In conclusion, the present study is unable to show a superiority of rESWT once weekly for a total of three weeks at 10 Hz frequency, 1.8 bar pneumatic pressure, and 2,000 pulses over supervised exercises with NMI in decreasing pain or improving function and grip strength at one and three months of follow-up in patients with LE. The differences in the use of shock waves (focused or radial), the number of sessions and frequency, and differences of device parameters (pulses, energy levels, frequencies, or pressures) may limit the implications of the results of our study. The optimal treatment protocol of rESWT in LE must be identified for optimal effects in future studies with the inclusion of a larger number of patients using a large-scale interventional research.

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REFERENCES

- Sanders TL Jr, Maradit Kremers H, Bryan AJ, Ransom JE, Smith J, Morrey BF. The epidemiology and health care burden of tennis elbow: a population-based study. *Am J Sports Med* 2015;43:1066-71.
- Shiri R, Viikari-Juntura E. Lateral and medial epicondylitis: role of occupational factors. *Best Pract Res Clin Rheumatol* 2011;25:43-57.
- Faro F, Wolf JM. Lateral epicondylitis: review and current concepts. *J Hand Surg Am* 2007;32:1271-9.
- Kraushaar BS, Nirschl RP. Tendinosis of the elbow (tennis elbow). Clinical features and findings of histological, immunohistochemical, and electron microscopy studies. *J Bone Joint Surg [Am]* 1999;81:259-78.
- Dingemans R, Randsdorp M, Koes BW, Huisstede BM. Evidence for the effectiveness of electrophysical modalities for treatment of medial and lateral epicondylitis: a systematic review. *Br J Sports Med* 2014;48:957-65.
- Pattanittum P, Turner T, Green S, Buchbinder R. Non-steroidal anti-inflammatory drugs (NSAIDs) for treating lateral elbow pain in adults. *Cochrane Database Syst Rev* 2013;2013:CD003686.
- Coombes BK, Bisset L, Vicenzino B. Efficacy and safety of corticosteroid injections and other injections for management of tendinopathy: a systematic review of randomised controlled trials. *Lancet* 2010;376:1751-67.
- Cullinane FL, Boocock MG, Trevelyan FC. Is eccentric exercise an effective treatment for lateral epicondylitis? A systematic review. *Clin Rehabil* 2014;28:3-19.
- Reilly JM, Bluman E, Tenforde AS. Effect of Shockwave Treatment for Management of Upper and Lower Extremity Musculoskeletal Conditions: A Narrative Review. *PM R* 2018;10:1385-403.
- Carulli C, Tonelli F, Innocenti M, Gambardella B, Muncibi F, Innocenti M. Effectiveness of extracorporeal shockwave therapy in three major tendon diseases. *J Orthop Traumatol* 2016;17:15-20.
- Speed C. A systematic review of shockwave therapies in soft tissue conditions: focusing on the evidence. *Br J Sports Med* 2014;48:1538-42.
- d'Agostino MC, Craig K, Tibalt E, Respizzi S. Shock wave as biological therapeutic tool: From mechanical stimulation to recovery and healing, through mechanotransduction. *Int J Surg* 2015;24:147-53.
- Buchbinder R, Green SE, Youd JM, Assendelft WJ, Barnsley L, Smidt N. Shock wave therapy for lateral elbow pain. *Cochrane Database Syst Rev* 2005;(4):CD003524.
- Rompe JD, Maffulli N. Repetitive shock wave therapy for lateral elbow tendinopathy (tennis elbow): a systematic and qualitative analysis. *Br Med Bull* 2007;83:355-78.
- Palmer K, Walker-Bone K, Linaker C, Reading I, Kellingray S, Coggon D, et al. The Southampton examination schedule for the diagnosis of musculoskeletal disorders of the upper limb. *Ann Rheum Dis* 2000;59:5-11.
- Sarkar B, Das PG, Equebal A, Mitra PK, Kumar R, Anwer S. Efficacy of low-energy extracorporeal shockwave therapy and a supervised clinical exercise protocol for the treatment of chronic lateral epicondylitis: A randomised controlled study. *Hong Kong Physiotherapy Journal* 2013;31:19-24.
- Poltawski L, Watson T. Measuring clinically important change with the Patient-rated Tennis Elbow Evaluation. *Hand Therapy* 2011;16:52-7.
- Capan N, Esmailzadeh S, Oral A, Basoglu C, Karan A, Sindel D. Radial extracorporeal shock wave therapy is not more effective than placebo in the management of lateral epicondylitis: A Double-Blind, Randomized, Placebo-Controlled Trial. *Am J Phys Med Rehabil* 2016;95:495-506.
- Radwan YA, ElSobhi G, Badawy WS, Reda A, Khalid S. Resistant tennis elbow: shock-wave therapy versus percutaneous tenotomy. *Int Orthop* 2008;32:671-7.
- Gündüz R, Malas FÜ, Borman P, Kocaoglu S, Özçakar L. Physical therapy, corticosteroid injection, and extracorporeal shock wave treatment in lateral epicondylitis. Clinical and ultrasonographical comparison. *Clin Rheumatol* 2012;31:807-12.

21. Ozturan KE, Yucel I, Cakici H, Guven M, Sungur I. Autologous blood and corticosteroid injection and extracorporeal shock wave therapy in the treatment of lateral epicondylitis. *Orthopedics* 2010;33:84-91.
22. Rompe JD, Cacchio A, Weil L Jr, Furia JP, Haist J, Reiners V, et al. Plantar fascia-specific stretching versus radial shock-wave therapy as initial treatment of plantar fasciopathy. *J Bone Joint Surg [Am]* 2010;92:2514-22.
23. Chung B, Wiley JP, Rose MS. Long-term effectiveness of extracorporeal shockwave therapy in the treatment of previously untreated lateral epicondylitis. *Clin J Sport Med* 2005;15:305-12.
24. Köksal İ, Güler O, Mahiroğulları M, Mutlu S, Çakmak S, Akşahin E. Comparison of extracorporeal shock wave therapy in acute and chronic lateral epicondylitis. *Acta Orthop Traumatol Turc* 2015;49:465-70.
25. van der Worp H, van den Akker-Scheek I, van Schie H, Zwerver J. ESWT for tendinopathy: technology and clinical implications. *Knee Surg Sports Traumatol Arthrosc* 2013;21:1451-8.
26. Spacca G, Necozone S, Cacchio A. Radial shock wave therapy for lateral epicondylitis: a prospective randomised controlled single-blind study. *Eura Medicophys* 2005;41:17-25.
27. Yang TH, Huang YC, Lau YC, Wang LY. Efficacy of radial extracorporeal shock wave therapy on lateral epicondylitis, and changes in the common extensor tendon stiffness with pretherapy and posttherapy in real-time sonoelastography: A Randomized Controlled Study. *Am J Phys Med Rehabil* 2017;96:93-100.
28. Malliaropoulos N, Crate G, Meke M, Korakakis V, Nauck T, Lohrer H, et al. Success and recurrence rate after radial extracorporeal shock wave therapy for plantar fasciopathy: a retrospective study. *Biomed Res Int* 2016;2016:9415827.
29. Malliaropoulos N, Thompson D, Meke M, Pyne D, Alaseirlis D, Atkinson H, et al. Individualised radial extracorporeal shock wave therapy (rESWT) for symptomatic calcific shoulder tendinopathy: a retrospective clinical study. *BMC Musculoskelet Disord* 2017;18:513.
30. Stasinopoulos D, Stasinopoulos I, Pantelis M, Stasinopoulou K. Comparison of effects of a home exercise programme and a supervised exercise programme for the management of lateral elbow tendinopathy. *Br J Sports Med* 2010;44:579-83.
31. Rompe JD, Furia J, Maffulli N. Eccentric loading versus eccentric loading plus shock-wave treatment for midportion achilles tendinopathy: a randomized controlled trial. *Am J Sports Med* 2009;37:463-70.