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Orgınal Article

The Efficacy of Large-Focused and Controlled-Unfocused (Radial) Extracorporeal Shock Wave Therapies in the treatment of Patellar Tendinopathy: A randomized sham-controlled single-blind trial

Patellar Tendinopati tedavisinde Geniş Odaklı ve Kontrollü Odaksız (Radyal) Ekstrakorporeal Şok Dalgası Tedavilerinin Etkinliği: Randomize sham-kontrollü tek kör çalışma

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Abstract

Background: Although Extracorporeal Shock Wave Therapy (ESWT) is a widely used treatment option in patellar tendinopathy (PT), treatment protocols are not clearly defined. There is no consensus on the type of shock wave or the energy level, number of shocks, pressure, and frequency values. For this reason, this study will, on the one hand, aim to contribute to the confusion of whether ESWT is effective in the treatment of PT and, on the other hand, try to define the most effective ESWT protocol in the treatment of PT, rather than choosing one at random. **Methods:** Eighty-six patients with PT randomised to 'Controlled Unfocused/Radial' ESWT (r-ESWT), 'Large-Focused' ESWT (f-ESWT) and sham ESWT (s-ESWT) groups and the data of seventy-eight patients who could reach the last control were evaluated statistically. The patients received the ESWT application once a week for a total of three sessions. Patients were evaluated with Visual Analog Scale (VAS) and Victorian Institute of Sports Assessment-Patella (VISA-P) scores just before the treatment (baseline), one day after the end of treatment (week 3), one month after the end of treatment (week 7) and three months after the end of treatment (week 15).**Results:** VAS and VISA-P scores have significantly improved at *3th, 7th, and 15th weeks* in the r-ESWT group ($p<0.05$) and at *7th, and 15th weeks* in the f-ESWT group ($p<0.05$). In terms of *baseline-3th week, baseline-7th week and baseline-15th* week differences of VAS and VISA-P scores, r-ESWT was superior to f-ESWT ($p<0.05$). **Conclusions:** Although both r-ESWT and f-ESWT were effective in the treatment of PT according to the results of this study, the efficacy of r-ESWT was superior to f-ESWT.

KeyWords: patellar tendinopathy, extracorporeal shock wave therapy, radial, focused

ÖZ

Amaç: Patellar tendinopati (PT) tedavisinde yaygın olarak kullanılmasına rağmen Vücut Dışı Şok Dalga Tedavisi-Extracorporeal Shock Wave Therapy (ESWT) 'nin tedavi protokolleri net olarak tanımlanmamıştır. Şok dalgasının türü (odaklanmış veya radyal), enerji seviyesi, atım sayısı, basınç ve frekans değerleri hakkında fikir birliği sağlanamamıştır. Bu nedenle bu çalışma bir yandan ESWT'nin PT tedavisinde etkili olup olmadığı konusundaki karışıklığa katkıda bulunmayı, diğer yandan PT tedavisinde rastgele bir ESWT tedavisi seçmek yerine en etkili ESWT protokolünü tanımlamayı amaçlamaktadır. **Yöntemler:** Seksen altı PT hastası; Radial-Radyal ESWT (r-ESWT), Focused-Odaklı ESWT (f-ESWT) ve Sham-Plasebo ESWT (s-ESWT) gruplarına randomize edildi ve son kontrole ulaşabilen yetmiş sekiz hastanın verileri istatistiksel olarak değerlendirildi. ESWT, birer hafta arayla uygulanan toplam üç seans olarak uygulandı. Hastalar tedaviden hemen önce (başlangıçta), tedavi bitiminden bir gün sonra (3. hafta), tedavi bitiminden bir ay sonra (7. hafta) ve tedavi bitiminden üç ay sonra (15. hafta) Görsel Analog Skala-Visual Analogue Scale (VAS) ve Viktorya Enstitüsü Spor Değerlendirme-Diz kapağı-Victorian Institute of Sports Assessment-Patella (VISA-P) skorları ile değerlendirildi. **Bulgular:** VAS ve VISA-P skorları, r-ESWT grubunda 3., 7. ve 15. haftalarda ($p<0.05$), f-ESWT grubunda ise 7. ve 15. haftalarda anlamlı olarak iyileşti ($p<0.05$). VAS ve VISA-P skorlarının başlangıç-3. hafta, başlangıç-7. hafta ve başlangıç-15. hafta farkları açısından r-ESWT, f-ESWT'den üstündü ($p<0.05$). s-ESWT grubunda takip haftalarının hiçbirinde VAS ve VISA-P skorlarında anlamlı değişiklik olmadı ($p>0,05$). **Sonuç:** Bu çalışmanın sonuçlarına göre PT tedavisinde hem r-ESWT hem de f-ESWT etkili olsa da r-ESWT'nin etkinliği f-ESWT'den üstün bulundu.

Anahtar Kelimeler: patellar tendinopati, vücut dışı şok dalga terapisi, radyal, odaklı

Highlights

• ESWT is a promising option in the treatment of patellar tendinopathy.

• Finding out which ESWT type is more effective in the treatment of patellar tendinopathy is important for treatment success.

INTRODUCTION

Patellar Tendinopathy (PT) is an injury that causes pain and dysfunction in the patellar tendon and is usually caused by overload (1). A localized pain is usually felt in the proximal patellar tendon during jumping and squatting activities (2). Although the overall prevalence among competitive elite athletes is 14%, it can reach 45% among volleyball and basketball players (3).

The conservative treatment of PT is carried out with two options: active and passive. Active conservative treatment includes eccentric, isometric, and resistance exercises. Passive treatment options include NSAIDs, corticosteroid and platelet-rich plasma (PRP) injections, iontophoresis, topical glyceryl trinitrate (GTN), low-energy laser, therapeutic ultrasound (US), and extracorporeal shockwave therapy (ESWT) (4).

ESWT is a high-energy sound wave therapy that enhances the healing of damaged tissues. It was first used in the treatment of kidney stones and has been used in the treatment of musculoskeletal disorders of tendons, ligaments, muscles, joints, and bones since the 1990s (5).

It is very encouraging that, in a systematic review, approximately 74.7% of those who underwent ESWT in the treatment of PT had improvements in pain and knee function, and no serious side effects were reported (6). However, in some other studies, its effectiveness has not been proven (7,8) and this makes it difficult to reach a definite conclusion. In addition, ESWT treatment protocols have not been clearly established. In different studies, the type of shock wave (radial (r-) ESWT or focused (f-) ESWT), energy level, number of shocks, pressure, and frequency values varied. (9–12). Only one study has compared the r- and f- waves in the treatment of PT (13).

For this reason, this study will, on the one hand, aim to contribute to the confusion of whether ESWT is effective in the treatment of PT and, on the other hand, try to define the most effective ESWT protocol in the treatment of PT, rather than choosing one at random.

MATERIALS AND METHODS

Ethical Considerations

All patients were informed verbally before the study, and all of them filled out written informed consent forms in accordance with the Declaration of Helsinki. Yüzüncü Yıl University Clinical Research Ethics Committee approval was obtained (Decision No: 02; Date: June 06, 2022) and registered on 'Clinicaltrials.gov' with the number NCT05423366.

Study Design

This study was carried out at the University of Van Yüzüncü Yıl, Faculty of Medicine, Department of Sports Medicine, and it was a prospective, single-blind, randomized, and sham-controlled clinical trial with three parallel treatment groups; Controlled-Unfocused (Radial) ESWT (r-ESWT), Large-Focused ESWT (f-ESWT), and Sham ESWT (s-ESWT). The study lasted for fifteen weeks, of which the first three weeks were the treatment period. Patients in all three groups were given isometric knee exercises as a home program until the end of the ESWT sessions (during the first 3 weeks of the study). Patients were evaluated with Visual Analog Scale (VAS) and Victorian Institute of Sports Assessment-Patella (VISA-P) scores just before the treatment (baseline), one day after the end of treatment (week 3), one month after the end of treatment (week 7) and three months after the end of treatment (week 15). In patients with bilateral knee pain, treatments were applied to both sides, but evaluations were made based on the most painful knee.

Estimation of Sample Size

The study power and sample size were calculated with a study power of 80% and a 5% type 1 (α) error with the G*Power statistical program (version 3.1.9.7).

Participants

A total of 100 patients (66 volleyball athletes and 34 basketball athletes) were evaluated in terms of inclusion and exclusion criteria. Eighty-six patients, who accepted to participate in the study and met the criteria, randomised to 'Controlled Unfocused/Radial' ESWT (r-ESWT), 'Large-Focused' ESWT (f-ESWT) and sham ESWT (s-ESWT) groups. The statistical results of 78 patients that were able to be evaluated at the last control were analyzed. Figure 1 shows the flowchart of the study participants.

Inclusion criteria were: being 18-40 years old, doing sports at least once a week, and being diagnosed with PT. The PT was diagnosed by the physiatrist in the presence of the following findings: knee pain in the patellar tendon or its insertion, tenderness along the patella tendon or in the insertion of the tendon into the patella, symptoms for more than 8 weeks, VISA-P score at the baseline (before treatment) less than 80, pain that limited to the tendon or tendon-bone junction during loading and does not radiate to the entire patellar region (to differentiate PT and patellofemoral pain). In bilateral complaints, treatment was applied to both knees, but the most painful knee was included in the study. Exclusion criteria were: acute knee injury, chronic inflammatory joint diseases (such as rheumatoid arthritis), the other co-existing knee pathologies, use of corticosteroid drugs in the past 6 months, history of knee surgery (on the anterior cruciate ligament or patellar tendon), a recent injection of the knee (including corticosteroid) within one month, contraindications for ESWT treatment (e.g., malignancy, coagulopathy, pregnancy), and participants who had previously received ESWT (as they couldn't be blinded to ESWT).

Randomisation

The patients were assigned to the treatment groups by "block randomization" with the help of the "Random Allocation Software (ver.1.0)" package program.

Blinding

The patients were not informed about the sequence of procedures and their differences from each other. They did not realize which treatment group they were included in since ESWT had never been applied to them before, and similar pulse sounds were heard in all three groups of treatment.

Interventions

The patients received the ESWT application once a week for a total of three sessions. The probe was applied to the most painful point on the patellar tendon when the patient brought the knee to full extension in the supine position with an ultrasound gel, and without using local anesthesia. The same ESWT device was used in all sessions and in both treatment groups (Pagani Elettronica, made in Italy) and it has an electro-pneumatic system and produces both r- and f- waves. The frequency, pressure, energy, pulse, and duration values when hip osteoarthritis diagnosis is selected on the screen were automatically assigned by the device.

The f-ESWT was applied to the first group as two consecutive parts in each session; part 1 (5 Hz, 1.6 Bar, 500 pulses, 0.02-0.60 mJ/mm2, 1 minutes and 40 seconds) + part 2 (8 Hz, 1.8 Bar, 1800 pulses, 0.02-0.60 mJ/mm2, 3 minutes and 45 seconds. The r-ESWT was applied to the second group as two consecutive parts in each session; part 1 (5 Hz, 1.4 Bar, 1400 pulses, 0.168 mJ/mm2, 4 minutes and 40 seconds) + part 2 (8 Hz, 1.5 Bar, 1800 pulses, 0.180 mJ/mm2, 3 minutes and 45 seconds). The s-ESWT was applied to the third group. For the s-ESWT application, using an r-ESWT probe, the frequency (Hz), pressure (Bar) values, and time intervals are the same as the r-ESWT, but the energy value (joule) was manually set to 0 (zero) so that there was no energy transfer to the patient.

Outcome Measures

The pain intensity of the patients at rest was evaluated by the VAS. This scale consists of a horizontal line, the value of 0 (zero-no pain) at the beginning of the line, and the value of 10 (ten-unbearable pain) at the end.

The VISA-P questionnaire is an outcome assessment scale for PT patients (14) and is used to evaluate pain and activity level. It is scored between 0 and 100 (no activity/maximum pain = 0 and maximum activity/no pain = 100). The Turkish validity and reliability was demonstrated by Çelebi et al. (15).

Statistical analysis

After the normal distribution control for continuous measurements was evaluated with the Shapiro-Wilk ($n<50$) and Skewness-Kewness tests, parametric tests were applied for measurements that were found to be normally distributed. Descriptive statistics for continuous variables are expressed as a mean (mean), standard deviation (SD), number (n), and percentage (%). The "Independent T-test" and "One-Way ANOVA" were used to compare continuous measurement values according to the treatment groups. The "paired T-test" was used to compare the VAS and VISA-P changes over time. The statistical significance level was taken as $p<0.05$ in calculations, and SPSS (IBM SPSS for Windows, ver.26) statistical package program was used for analysis.

RESULTS

Table 1 presents the participants' characteristics. The groups were similar with respect to baseline characteristics (age, gender, height, weight, body mass index, distribution of sport type, and symptom duration) (for all, $p>0.05$) (Table 1). Also, the three groups were similar in terms of baseline VAS and VISA-P scores (for all, $p>0.05$) (Tables 2-3).

Intra-group comparisons

VAS and VISA-P scores have significantly changed (improved) at all follow-up points (*3^{th}, 7^{th}, and 15^{th} weeks*) compared with baseline (0^{th} week), in the r-ESWT group ($p<0.05$). VAS and VISA-P scores have significantly

changed (improved) at two follow-up points (*7th, and 15th weeks*) compared with baseline (0th week), in the f-ESWT group (p<0.05). VAS and VISA-P scores have not significantly changed in any of the follow-up points in the s-ESWT group (p>0.05) (Tables 2-3).

Table 1. Statistical analysis of the participants characteristics.

		f-ESWT		r-ESWT		s-ESWT		*P
		n	%	n	%	n	%	
Gender	Female	15	34.1%	15	34.1%	14	31.8%	*0.930*
	Male	11	32.4%	13	38.2%	10	29.4%	
Sports Type	Basketball	10	29.4%	12	35.3%	12	35.3%	*0.710*
	Volleyball	16	36.4%	16	36.4%	12	27.3%	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	***P**
Age		26.22	5.57	24.76	4.58	26.55	5.10	*0.397*
Height (meter)		1.77	0.10	1.77	0.08	1.77	0.09	*0.941*
Weight (kg)		74.42	14.07	71.35	12.24	70.97	13.39	*0.592*
Body Mass Index (kg/m^2)		23.60	2.26	22.70	2.23	22.35	2.35	*0.135*
Symptom Duration (week)		23.88	12.33	23.46	12.64	28.00	13.37	*0.386*

** chi-square test; ** independent T-test f-ESWT: Focused Extracorporeal Shock Wave Therapy. r-ESWT: Radial Extracorporeal Shock Wave Therapy s-ESWT: Sham Extracorporeal Shock Wave Therapy*

Table 2. Statistical analysis for the VAS scores.

	f-ESWT			r-ESWT			s-ESWT			*p.
	Mean	**SD**	***p.**	**Mean**	**SD**	***p.**	**Mean**	**SD**	***p.**	
Base VAS	5.85	1.22		5.75	1.27		5.58	1.32		*0.762*
Week3 VAS	5.81a	1.36		3.04b	2.03		5.00a	1.64		***0.001***
Week7 VAS	4.62a	1.27		1.64b	1.66		5.25a	1.33		***0.001***
Week 15VAS	4.23b	1.24		1.07c	1.70		5.21a	1.47		***0.001***
Change (Base-Week3 VAS	0.04b	1.18	*0.870*	2.71a	2.49	***0.001***	0.58b	1.56	*0.080*	***0.001***
Change (Base-Week7 VAS	1.23b	1.07	***0.001***	4.11a	2.17	***0.001***	0.33c	0.92	*0.088*	***0.001***
Change (Base-Week 15 VAS	1.62b	1.10	***0.001***	4.68a	2.28	***0.001***	0.38c	0.97	*0.071*	***0.001***

** ANOVA test (inter-groups comparisons) ** Dependent (paired) T-test (inta-group comparisons).VAS: Visual Analog Scale. f-ESWT: Focused Extracorporeal Shock Wave Therapy. r-ESWT: Radial Extracorporeal Shock Wave Therapy.. s-ESWT: Sham Extracorporeal Shock Wave Therapy*

Table 3. Statistical analysis for the VISA-P scores.

	f-ESWT			r-ESWT			s-ESWT			*p.
	Mean	**SD**	***p.**	**Mean**	**SD**	***p.**	**Mean**	**SD**	***p.**	
Base VISA-P	55.89	10.26		56.75	11.36		56.54	10.43		*0.955*
Week3 VISA-P	56.95b	11.75		74.25a	11.44		60.21b	12.40		*0.001*
Week7 VISA-P	66.87b	10.24		83.18a	9.33		57.71c	10.34		*0.001*
Week15 VISA-P	72.85b	11.47		89.36a	8.64		57.08c	10.95		*0.001*
Change (Base-Week3 VISA-P	-1.05a	8.01	*0.508*	-17.50b	15.76	*0.001*	-3.67a	11.44	*0.130*	*0.001*
Change (Base-Week7 VISA-P	-10.98b	9.33	*0.001*	-26.43c	14.97c	*0.001*	-1.17a	7.25	*0.439*	*0.001*
Change (Base-Week15 VISA-P	-16.96b	10.47	*0.001*	-32.61c	14.88	*0.001*	0-.54a	5.93	*0.659*	*0.001*

** ANOVA test (inter-groups comparisons). ** Dependent (paired) T-test (inta-group comparisons). VISA-P: The Victorian Institute of Sport Assessment-Patella. f-ESWT: Focused Extracorporeal Shock Wave Therapy. r-ESWT: Radial Extracorporeal Shock Wave Therapy. s-ESWT: Sham Extracorporeal Shock Wave Therapy*

Inter-groups comparisons

In terms of *baseline-3th week. baseline-7th week and baseline-15th* week differences of VAS and VISA-P scores. r-ESWT was superior to s-ESWT (p<0.05). In terms of *baseline-7th week and baseline-15th week* differences of VAS and VISA-P scores. f-ESWT was superior to s-ESWT (p<0.05). Importantly. in terms of *baseline-3th week. baseline-7th week and baseline-15th* week differences of VAS and VISA-P scores. r-ESWT was superior to f-

ESWT ($p<0.05$) (Tables 2-3). Mild erythema. which improved one day after the first session. was detected in 3 patients in the f-ESWT group and in 1 patient in the r-ESWT group. but this side effect did not occur in the other sessions that followed.

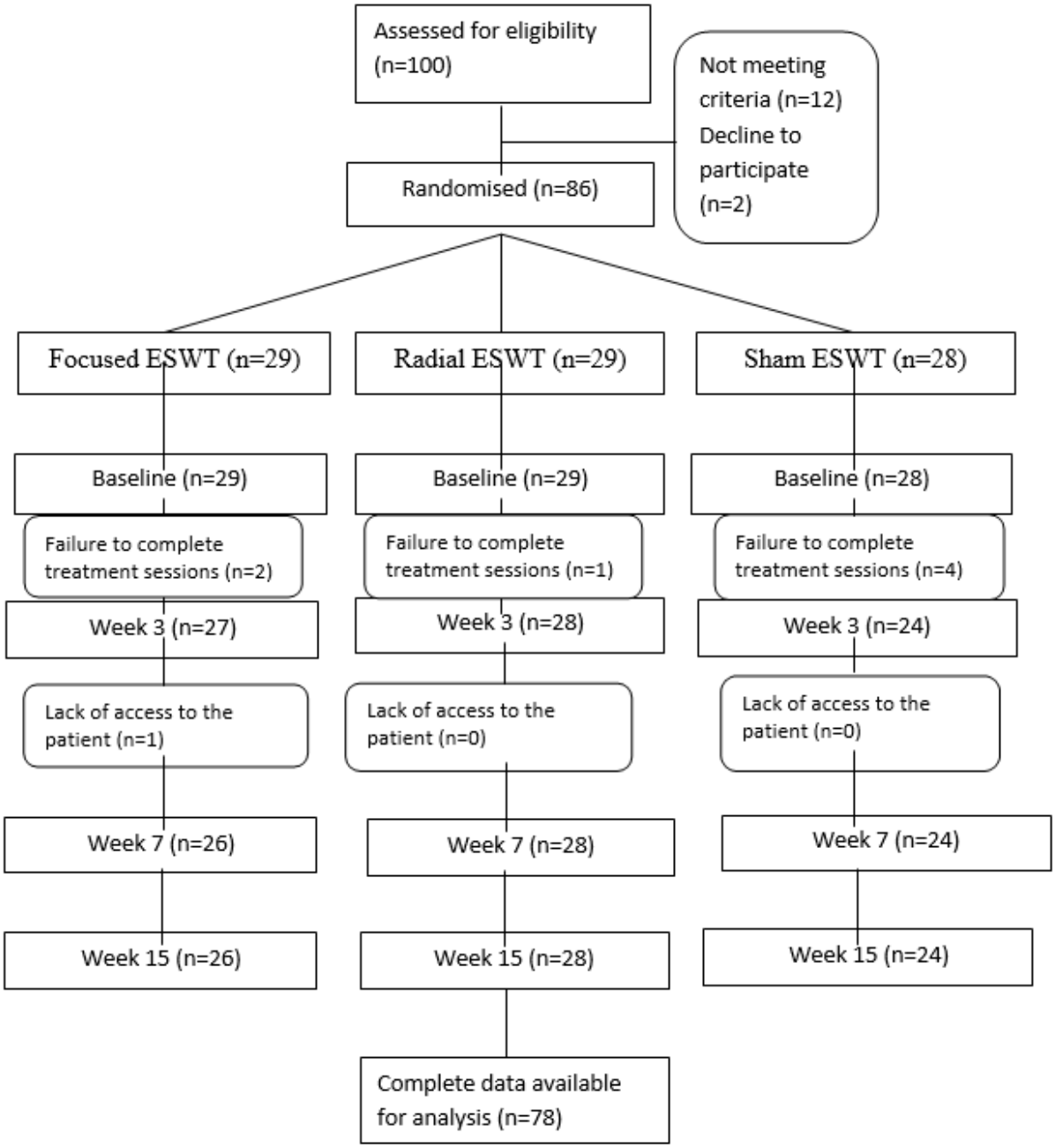

Figure 1. Flowchart of the study participants.

DISCUSSION

This randomized. controlled. single-blind study demonstrated that ESWT might be an effective and safe option for treating patients with patellar tendinopathy. According to pain and activity level assessment based on VAS and VISA-P scores. both the f-ESWT and r-ESWT were found to be effective in the treatment of patellar tendinopathy. However; the f-ESWT provided a superior improvement in these scores compared to the r-ESWT based on mid-term outcomes.

Despite conflicting results on the effectiveness of ESWT. it is widely used in sports injuries. The precise mechanisms of ESWT's pain-relieving effect are unknown; however. it has been proposed that ESWT improves

tissue healing by increasing TGF1 and IGF-1 expression. and that it may also induce neovascularization by increasing the release of endothelial nitric oxide synthase and vascular endothelial growth factor (16). However. ESWT could also have some side effects such as dysesthesia. swelling. ecchymosis and/or petechiae. bruising. and a throbbing sensation (17).

The therapeutic efficacy of ESWT for patellar tendinopathy is unclear (18). The studies in a systematic review about the efficacy of ESWT in the treatment of patellar tendinopathy indicated that ESWT produced both short- and long-term improvements (19). However. another systematic review is available in the literature with contradictory results. concluding that ESWT is not superior to standard conservative treatments (20).

In the study conducted to treat patellar tendinopathy patients consisting of volleyball. basketball. and handball athletes. f-ESWT was applied three sessions per week at a frequency of 4 Hz per session. with 2000 shocks and energy flow up to a maximum of 0.58 mJ/mm2 (according to the pain tolerance of each patient). Although the patients' symptoms decreased in the first week. it was revealed that there was no positive change in the pain and function evaluations at the 12^{th} and 22^{nd} weeks (7). Cheng et al. in their study on athletes with patellar tendinopathy. compared the r-ESWT (16 weekly sessions. 2000 shocks per session; 1.5 to 3.0 bar pressure; 9 to 12 Hz frequency) and the control group (patients receiving physical therapy such as acupuncture. ultrasonic wave. and microwave therapy). Significant improvements in pain and muscle strength scores were demonstrated in both treatment groups at week 16 (21).

The first comparison study of the r-ESWT and f-ESWT in the treatment of patellar tendinopathy was conducted by Van der Worp et al. A significant improvement in VAS and activity scores was observed at 14 weeks in both the group given eccentric exercise + three sessions of r-ESWT and the group given eccentric exercise + three sessions of f-ESWT. but no statistically significant difference was found between the groups (13).

The studies in which PT was treated with either r-ESWT or f-ESWT predominate in the literature (7.19–21). Only one trial has examined the comparative effects of r-ESWT and f-ESWT in the treatment of PT. and it became a milestone in further identifying the most effective ESWT type for each musculoskeletal disease. In this study. researchers applied f-ESWT at a frequency of 4 Hz and an energy level of 0.12 mJ/mm^2. and r-ESWT at a frequency of 8 Hz and a pressure of 2.4 bars. Both groups received electro-magnetic ESWT once a week for a total of 3 sessions and 2000 shocks per session (13). In our trial. unlike this study. we found r-ESWT to be superior to the f-ESWT. Since our frequency. energy and pressure values were similar. the difference could be considered in our study that the number of pulses per session is higher in the r-ESWT (3200 pulses) than in the f-ESWT (2300 pulses). and that our device was electro-pneumatic. unlike their electro-magnetic device.

Due to their characteristics. f-ESWT waves reach higher energy levels in deeper tissues. while r-ESWT gives its maximum energy just near the probe tip (22). In our study. although the energy density could increase up to 0.60 mj/mm2 in certain sequences during the f-ESWT session. the fact that r-ESWT was more effective may be related to the superficial location of the patellar tendon. In addition. because our electro-pneumatic device (Pagani Elettronica. Italy) delivered 3200 shocks per session in the r-ESWT group and 2300 shocks in the f-ESWT group. a higher number of pulses may have resulted in more positive treatment results. Pressure (bar) and frequency (Hz) values were similar in both treatment groups. suggesting that they did not have an effect on different treatment outcomes.

Limitations

This study had some limitations. The treatment groups were non-homogeneous as they included both men and women. No radiological imaging (X-ray. MRI. etc) was taken from the patients. For follow-up. no athletic performance tests were used. Further studies can be conducted with larger patient series and longer follow-up periods.

CONCLUSIONS

In terms of VAS and VISA-P scores. both the r-ESWT which created a significant difference at the 3^{th}.5^{th} and 17^{th} weeks. and the f-ESWT which created a significant difference at the 5^{th} and 17^{th} weeks. were found to be effective in the treatment of PT. However. the r-ESWT produced a superior improvement at follow-up points (3^{th}.5^{th} and 17^{th} weeks) compared to the f-ESWT.

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Author Contributions: *Concept: VŞ. Literature Review: VŞ. VD Design: VŞ. VD. Data acquisition: VŞ. VD Analysis and interpretation: VŞ. VD Writing manuscript: VŞ Critical revision of manuscript: VŞ. VD*

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