Turk J Phys Med Rehab 2023;69(1):97-104
DOI: 10.5606/tftrd.2023.10371
Available online at www.turkishjournalpmr.com

Original Article

Comparative effects of radial and focused extracorporeal shock wave therapies in coccydynia

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Received: December 22, 2021 **Accepted:** October 18, 2022 **Published online:** February 04, 2023

ABSTRACT

Objectives: This study was conducted to compare the effects of radial and focused extracorporeal shock wave therapy (ESWT) in patients with coccydynia.

Patients and methods: In this prospective randomized double-blind study conducted between March 2021 and October 2021, 60 patients with coccydynia (50 males, 10 females; mean age: 35.9±12.0 years, range 18 to 65 years) were randomized into three groups (n=20) according to different wave types of ESWT: focused, radial, and sham. The Visual Analog Scale (VAS) was used for pain assessment, and the Oswestry Disability Index (ODI) was used for functional assessment in all patients before the treatment (baseline), after the completion of four sessions of treatment (fourth week), one month after the end of the treatment (eighth week), and three months after the end of the treatment (16th week).

Results: The mean body mass index of the participants was 26.2±3.0. Compared to baseline, the VAS scores at four weeks were reduced only in the radial ESWT group ($p<0.05$). Compared to baseline, the VAS and ODI scores at eight and 16 weeks were significantly reduced in both the focused and radial ESWT groups ($p<0.05$ for all). The radial ESWT group was significantly superior to the focused ESWT group in the comparisons between the groups at four weeks in the VAS values and at 16 weeks in the ODI scores ($p<0.05$ for all).

Conclusion: Radial and focused ESWT are both effective in treating coccydynia compared to sham ESWT. However, radial ESWT may be more effective in the treatment of coccydynia.

Keywords: Coccydynia, focused ESWT, radial ESWT.

The coccyx is the most distal bone of the spine and got this name because it resembles the beak of a bird called cuckoo in Latin.[1] Pain in the coccyx area is called coccydynia. It can be aggravated by prolonged sitting and triggered while standing up, during defecation, and during sexual intercourse. Although it can be detected in individuals of all ages and sexes, the female/male ratio is approximately five to one, and it is more common in adolescents and adults compared to children.[2]

Extracorporeal shock wave therapy (ESWT) was based on the application of acoustic waves created outside the body to the desired surface of the body.[3] Extracorporeal shock wave therapy was first used in Germany in 1980 to break up urinary stones. The ESWT device was first applied in the treatment of orthopedic problems in 1993.[4] Extracorporeal shock wave therapy is now widely used in the treatment of musculoskeletal disorders, such as a calcaneal spur, lateral epicondylitis,

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Cite this article as:
Şah V, Elasan S, Kaplan Ş. Comparative effects of radial and focused extracorporeal shock wave therapies in coccydynia. Turk J Phys Med Rehab 2023;69(1):97-104. doi: 10.5606/tftrd.2023.10371.

patellar tendonitis, Achilles tendinitis, and calcific shoulder tendinitis.[5,6]

There are pharmacological, conservative, and surgical options in the treatment of coccydynia. Nonsteroidal anti-inflammatory drugs are generally used in pharmacological treatment.[7] Partial or complete resection of the coccyx is performed in patients who do not respond to pharmacological and conservative treatments.[8] Conservative treatment options are sitting cushions, massage, stretching exercises, steroid injections, radiofrequency therapy, ganglion blocks, and ESWT.[9-11]

The treatment of coccydynia with ESWT was presented in the literature for the first time in 2014 as two case series.[12] This study of Marwan et al.[12] was followed by studies conducted by Lin et al.,[13] Haghighat et al.,[14] and Gönen Aydın et al.[7] Marwan et al.[15] expanded the number of patients and published a case series of 23 patients in 2017. It was concluded that ESWT improves pain and disability scores in the treatment of coccydynia in all these studies. The mechanism of ESWT in relieving the pain and disability of coccydynia is uncertain, but it is thought that shock waves initiate healing and repair through neovascularization and increase in blood flow.[4,16]

Shock waves in ESWT are defined as short duration (10 μs) and high pressure sound waves.[4] There are two types of shock waves used in ESWT, focused and radial. Focused shock waves (F-SW) are so named because they can focus to the desired tissue depth. Focused shock waves are produced in water since the sound permeability of normal tissue and water is similar. In this way, it is easier to pass to normal tissue. Radial shock waves (R-SW) owe their name to the radial dispersion of the generated pressure wave. Unlike F-SW, R-SW is not produced in water, it is obtained as a result of the compressed air passing through a tube and hitting the lead layer. While F-SW reaches its maximum energy level deeper, R-SW shows a more superficial effect. The pressure created by the R-SW reaches up to 40 mm in water, and the F-SW is stated to reach twice as far.[17,18]

Considering these differences in the way and depth of energy transmission between the two waves, we anticipated that there might be differences in the responses to the treatment applied with each type of wave. Instead of randomly choosing one of the two wave types, making a choice by predicting which is more effective will positively affect the treatment results. Although there have been publications on the treatment of coccydynia with ESWT,[7,12-14,19] there is no study comparing the treatment efficacy of these two different wave types. This study aimed to evaluate and compare the effectiveness of radial and focused ESWT in the treatment of coccydynia.

PATIENTS AND METHODS

This prospective randomized double-blind study was carried out with 60 patients (50 males, 10 females; mean age: 35.9±12.0 years, range 18 to 65 years) at the Department of Sports Medicine, Yüzüncü Yıl University School of Medicine between March 2021 and October 2021. The inclusion criteria for the study were having a pain duration between one and three months (subacute disease), confirming the diagnosis of coccydynia in clinical examination, not having a major fracture or dislocation requiring surgery on lateral radiographs, completing pre-and posttreatment follow-ups. Previous ESWT treatment, systemic comorbid diseases, such as hypertension and diabetes, musculoskeletal comorbid diseases, such as mechanical and rheumatological diseases of the low back and hips, sciatic pain for any reason, coagulation diseases, malignancies, infections, body implants, and inability to cooperate were determined as the exclusion criteria. Since fibromyalgia, pregnancy, psychiatric diseases, such as somatization disorders and depression, can also cause coccydynia,[7] patients with these disorders were excluded from the study.

Initially, a plan was made to randomize 69 patients into the three groups; two treatment (radial ESWT and focused ESWT) groups and a control (sham ESWT) group. However, a mandatory change was made due to the curfews related to the COVID-19 (coronavirus disease 2019) pandemic and the patients not applying to the hospital except for emergencies. When the number of patients in each group reached to 20, randomization was terminated for that group, and the number of patients in the other groups was completed to 20. Thus, each group consisted of 20 patients. The patients in all groups were given a single daily dose of 600 mg sustained-release etodolac orally at the same time for 10 days. All three groups were not using any other drug at the beginning of the treatment, and they were asked not to use it until the end of the study period (16th week). In addition, all patients used a seat cushion until the study period was completed (16th week), and activity restriction was suggested during the study.

The patients were not informed about the sequence of procedures and their differences from each other. A health personnel who was not involved in the study randomly assigned the participants to the treatment

groups. Researchers who did not participate in the collections evaluated the results. This allowed outcome evaluation to be blinded, which reduced the possibility of the study's detection bias. In addition, all results were fully recorded.

A total of four sessions of ESWT at one-week intervals were applied to the maximal tenderness of coccygeal area by the same physiotherapist and with the same device (Elettronica, Pagani, Italy) in side-lying position by bringing the hip and knee to the maximum flexion degree that the patients can achieve. Focused ESWT (8 Hz frequency, 1.8 bar pressure, 0.02-0.60 mJ/mm^2 energy, 1,500 pulses shock waves, 3 min 8 sec per session) was applied to the first group, radial ESWT (8 Hz frequency, 1.6 Bar pressure, 0.02-0.60 mJ/mm^2 energy, 1,500 pulses shock waves, 3 min 8 sec per session) was administered to the second group, and sham ESWT (1 Hz frequency, 1 bar pressure, 1500 pulses shock waves, 3 min 8 sec per session) was applied to the third group. In the sham ESWT, the energy value was manually set to zero so that no therapeutic energy was transmitted to the patient as it was a placebo application.

The severity of pain felt by the patients at rest and during activity was evaluated with the visual analog scale (VAS) from a scale of 0 (no pain) to 10 (worst possible pain). The patient was asked to mark the intensity of pain at rest or during activity on this scale.

Oswestry Disability Index (ODI) is a scale used to determine the functional level in low back pain. This questionnaire, which was developed by Howard Vernon and published in 1991,[20] includes activities such as personal care, walking, sitting, sleeping, standing, lifting weights, social life, and travel. The maximum score in the questionnaire is 100 points. An increase in score indicates an increase in functional limitation, while a decrease in score indicates an increase in functional level.[21] Turkish validity and reliability study of the ODI was published by Yakut et al.[22] in 2004.

The visual analog scale and ODI were initiated before the treatment (baseline), after the completion of four sessions of treatment (fourth week), one month after the end of the treatment (eighth week), and three months after the end of the treatment (16th week).

Sample size estimation

Since VAS was the primary variable in our study, the sample size (n) was calculated according to this parameter. According to the literature review, it was seen that the standard deviation for the VAS ranged between 0.9 and 1.3, and accordingly, the mean of the standard deviation was accepted as 1.1 in the calculation. In this context, type 1 error was 5% (Z=1.96), and effect size was d=0.5 (based on the value range of the effect size conventions for the F test). Sample size (population size unknown) was calculated as $n=(1.962\times1.12)/0.52=19$ according to the $n=(Z^2\times\sigma^2)/d2$ equation, 60 patients in total.

Statistical analysis

Data were analyzed using IBM SPSS version 26.0 (IBM Corp., Armonk, NY, USA). The Shapiro-Wilk (n<50) and skewness-kurtosis tests were used to check whether the continuous variables were normally distributed. Parametric tests were applied for normally distributed variables. In the study, descriptive statistics for continuous variables were expressed as mean and standard deviation for continuous variables. For VAS and ODI variables, analysis of variance with two factor was performed for comparison periods and groups. The Bonferroni multiple comparison test was also used to identify the differences among the groups and periods. The chi-square test was used to examine the association between categorical variables. A p value <0.05 was considered statistically significant.

RESULTS

The mean body mass index of the participants was 26.2±3.0 (range, 19.9 to 31.6). The age, body mass index, and sex distributions among the three groups were statistically similar (p=0.361, p=0.117, and p=0.432, respectively). General descriptive statistics of demographic variables are shown in Table 1. No side effects related to pharmacological treatment or ESWT were observed in any patient. General descriptive statistics according to the treatment groups are shown in Table 2. Intragroup and intergroup differences in VAS scores are demonstrated in Table 3. Although the mean VAS score at the fourth week in the focused ESWT group decreased compared to the baseline, this decrease was not statistically significant (p>0.05). However, the mean VAS values at the eighth and 16th weeks were found to be significantly lower compared to the baseline in the focused ESWT group (p<0.05). The mean VAS values in the radial ESWT group were found to be statistically significantly lower at the fourth, eighth, and 16th weeks compared to the baseline (p<0.05). There was no significant change in VAS scores at any control week in the sham ESWT group compared to baseline (p>0.05).

There was no statistically significant difference in VAS values between the three groups at the

TABLE 1
General descriptive statistics of demographic variables

	n	%	Mean±SD	Min-Max	*p*
Age (year)			35.9±12.0	18.0-65.0	
Body mass index (kg/m^2)			26.2±3.0	19.9-31.6	
Sex					
Female	50	83.3			
Male	10	16.7			
Type of ESWT					
Focused	20	33.3			
Radial	20	33.3			
Sham	20	33.3			
Disease duration (week)					0.092
Focused	8.15	1.69		6-12	
Radial	9.15	1.98		5-12	
Sham	8.00	1.62		5-11	

SD: Standard deviation; ESWT: Extracorporeal shock wave therapy.

TABLE 2
General descriptive statistics according to the treatment groups

	Focused ESWT			Radial ESWT			Sham ESWT			
	n	Row %	Column %	n	Row %	Column %	n	Row %	Column %	*p**
Age groups (year)										
18-35	12	37.5	60.0	8	25.0	40.0	12	37.5	60.0	
36-50	7	35.0	35.0	7	35.0	35.0	6	30.0	30.0	0.361
51-65	1	12.5	5.0	5	62.5	25.0	2	25.0	10.0	
Sex										
Female	15	30.0	75.0	18	36.0	90.0	17	34.0	85.0	0.432
Male	5	50.0	25.0	2	20.0	10.0	3	30.0	15.0	
BMI groups (kg/m^2)										
Normal	9	50.0	45.0	3	16.7	15.0	6	33.3	30.0	0.117
Overweight and obese	11	26.2	55.0	17	40.5	85.0	14	33.3	70.0	

ESWT: Extracorporeal Shock Wave Therapy; BMI: Body mass index; * Chi-square test statistics.

baseline (p>0.05). The mean VAS values at the fourth week was found higher in the focused ESWT group than that in the radial ESWT group (p<0.05). At the eighth and 16th weeks, focused and radial ESWT groups were statistically similar to each other (p>0.05), but only the radial ESWT group was superior to the sham ESWT group in terms of the mean VAS value (p<0.05). Visual analog scale changes according to control weeks are presented in Figure 1. Intragroup and intergroup differences of ODI scores are displayed in Table 4.

Although the mean ODI scores in the focused ESWT group showed a decrease at the fourth week compared to the baseline, this decrease was not statistically significant (p>0.05). Oswestry Disability Index scores were found to be significantly lower at the eighth and 16th weeks compared to the baseline in the focused ESWT group (p<0.05). Although the mean ODI scores in the radial ESWT group decreased at the fourth week compared to the baseline, this decrease was not statistically significant (p>0.05). Mean ODI scores were found to be significantly lower at the eighth and 16th weeks compared to the baseline in the radial ESWT group (p<0.05). No significant ODI change was detected in the sham ESWT group compared to the baseline at any control week (p>0.05).

No statistically significant difference was found between the groups in terms of ODI scores at the

TABLE 3
Comparison of VAS scores according to the wave types of ESWT

	Focused ESWT (n=20)	Radial ESWT (n=20)	Sham ESWT (n=20)	
	Mean±SD	Mean±SD	Mean±SD	*p**
Baseline VAS	7.6±1.7†	7.7±1.8†	6.7±2.2	0.160
4th week VAS	7.4±1.5[a]†	6.7±1.8[b]‡	5.9±2.0[b]	**0.035**
8th week VAS	5.2±2.0[ab]‡	4.3±1.6[b§]	5.7±1.8[a]	**0.041**
16th week VAS	4.2±2.0[ab]‡	3.1±1.7[b]	5.7±2.0[a]	**0.002**
***p*	0.001	0.001	0.087	

ESWT: Extracorporeal Shock Wave Therapy; VAS: Visual Analog Scale; * One way ANOVA test statistics; ** Repeated ANOVA test statistics; a,b,c: Shows the intergroup differences of VAS scores →; †,‡,§: Shows the intragroup differences of VAS scores ↓.

TABLE 4
Comparison of ODI scores according to the wave types of ESWT

	Focused ESWT (n=20)	Radial ESWT (n=20)	Sham ESWT (n=20)	
	Mean±SD	Mean±SD	Mean±SD	*p**
Baseline ODI	58.1±15.6†	57.6±18.1†	49.1±21.0	0.228
4th week ODI	55.2±17.2†	55.1±17.5†	47.4±20.9	0.320
8th week ODI	40.3±18.6‡	35.9±14.3‡	43.6±17.5	0.358
16th week ODI	33.6±16.9[a]§	21.8±13.8[b]§	39.8±18.4[a]	**0.004**
***p*	0.001	0.001	0.098	

ODI: Oswestry Disability Index; ESWT: Extracorporeal Shock Wave Therapy; * One way ANOVA test statistics; ** Repeated ANOVA test statistics; a,b: Shows the intergroup differences of VAS scores →; †,‡,§: Shows the intragroup differences of VAS scores ↓.

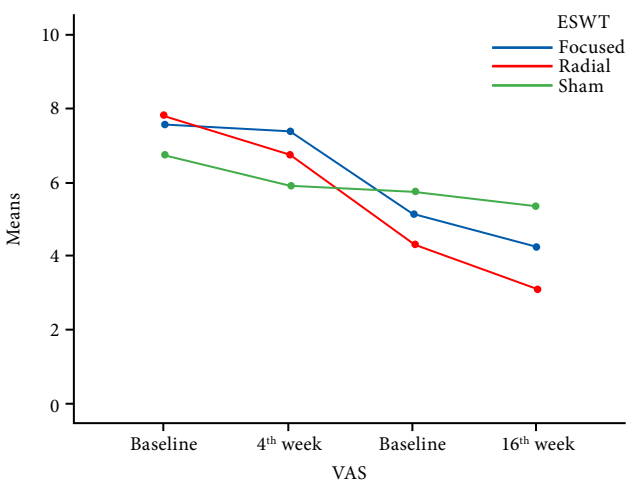

Figure 1. VAS changes in treatment groups according to the control weeks.
ESWT: Extracorporeal Shock Wave Therapy; VAS: Visual Analog Scale.

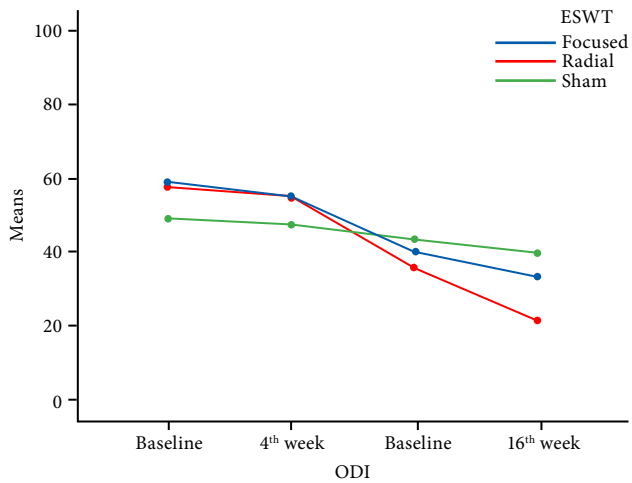

Figure 2. ODI changes in treatment groups according to the control weeks.
ESWT: Extracorporeal Shock Wave Therapy; ODI: Oswestry Disability Index.

baseline (p>0.05). Focused, radial, and sham ESWT groups were statistically similar to each other in terms of the mean ODI scores at the fourth and eighth weeks (p>0.05). The mean ODI scores at the 16th week were found significantly higher in the both the focused and sham ESWT groups than in the radial ESWT group (p<0.05) but were statistically to similar each other in the focused and sham groups (p>0.05). Oswestry Disability Index changes according to control weeks are shown in Figure 2.

DISCUSSION

Although there have been publications showing the efficacy of ESWT in the treatment of coccydynia in recent years,[7,12-15] there is no study comparing the efficacy of different ESWT waves in the treatment of coccydynia to date.

Extracorporeal shock wave therapy is the name given to the treatment with high-energy acoustic waves produced by electropneumatic (the device we used in this study), electrohydraulic, electromagnetic, or piezoelectric source devices.[23] Although the exact mechanisms about the pain-relieving effect of ESWT has not been elucidated, some hypotheses have been put forward. It was suggested that inflammatory changes are present in the coccygeal region in patients with coccydynia,[1] and ESWT has an anti-inflammatory effect by reducing inflammatory cytokines such as interleukins and matrix metalloproteinases.[24] Extracorporeal shock wave therapy has been shown to improve tissue healing by increasing TGF (tissue growth factor)-β1 and IGF (insulin-like growth factor)-1 expression.[25] It may also have a neovascularization-inducing effect by increasing the expression of vascular endothelial growth factor, endothelial nitric oxide synthase, and proliferating cell nuclear antigen.[26]

Gönen Aydın et al.[7] followed 34 patients with coccydynia up to six months after applying ESWT, and they found that focused ESWT (3,000 shockwaves of 0.2 mJ/mm^2 per session) reduced the VAS scores of the patients and showed improvement in physical function, social restraint, and general health parameters. Marwan et al.[12] found that VAS and NPS (numerical pain score) values decreased significantly until the first year after treatment of focused ESWT (3,000 shockwaves 0.2 mJ/mm^2) in the case reports of two patients with coccydynia. Lin et al.[13] compared radial ESWT (2,000 shockwaves of 5 Hz frequency and pressure of 3-4 bar per session) and physical modality in the treatment of coccydynia, and they found that VAS, ODI, and self-reported satisfaction scores decreased more significantly in the ESWT group until the eighth week after treatment. Haghighat et al.[14] noted that VAS scores decreased significantly in the early period (up to the second month) after applying radial ESWT (3,000 shock waves of 2 bar at 21 Hz frequency per session) to 10 patients with coccydynia. However, the decrease in VAS scores did not persist in the six-month control after the treatment. In another study by Marwan et al.,[15] they followed 23 patients with coccydynia for six months after the treatment of focused ESWT (3,000 shockwaves 0.2 mJ/mm^2), and the values of VAS and ODI scores at six months were found to be significantly lower than the baseline (before the treatment).

In these previous studies on the treatment of coccydynia with ESWT, it is of note that device frequencies were between 5 Hz and 21 Hz, pressures were between 2 and 4 bar, wave pulses were 2000 or 3000, and energy flux was set as 0.2 mJ/mm^2. In our study, the frequency value assigned by the device in both wave types (8 Hz) was similar to those in these studies, while the pressure values were 1.8 bar in focused ESWT and 1.6 bar in radial ESWT in the device we used. The slightly lower pressure and wave pulses (1,500 shockwaves) in our study may be due to the fact that we used a device (electropneumatic featured) that produces higher energy values (up to 0.6 mJ/mm^2 automatically) by requiring less pressure.

Focused and radial ESWT are both utilized, as observed in previous publications. However, it was not specified which ESWT wave type was chosen on what basis in these studies. Therefore, this randomized, double-blind, sham-controlled study was conducted to investigate which wave type would be more effective in the treatment of coccydynia with ESWT.

In this study, we found that both focused ESWT and radial ESWT were effective in the treatment of coccydynia, according to the comparisons of the VAS and ODI scores between pre-and posttreatment periods. However, radial ESWT may be the first choice since we found that radial ESWT was significantly superior to the focused ESWT group based on the comparisons between the groups at four weeks in the VAS values and at 16 weeks in the ODI scores.

Although waves have higher energy in focused ESWT, they affect a smaller area.[27] However, it should be aimed to spread the waves to the ligaments and muscles around the coccyx rather than a deep impact to a focused point because there is also pain and inflammation in the surrounding ligaments and

muscles in coccydynia, in addition to the pain of the coccyx itself.[28] Radial ESWT, which is suitable for this purpose,[17,18] can be preferred in patients with coccydynia.

Our study had some limitations. Only the patients in the subacute phase were included in the study. The cause of coccydynia in each patient was not investigated. Radiographs were taken only to distinguish the conditions requiring surgical intervention. Whether there was coccyx angulation or not and, if so, the directions and degrees were not recorded from radiographs. Advanced imaging techniques such as computed tomography or magnetic resonance imaging were not used. The treatment groups were nonhomogeneous as they included both males and females. Similar studies can be conducted with larger patient series and longer follow-up periods.

In conclusion, according to the results of our study, both wave types (radial and focused) were found to be effective up to the third month after applying four sessions of ESWT in patients with subacute coccydynia in terms of pain and function. However, more effective treatment results were obtained with radial ESWT compared to focused ESWT.

Ethics Committee Approval: The study protocol was approved by the Clinical Research Ethics Committee of Van Yüzüncü Yıl University (date: 29.01.2020, no: 05). Registered on Clinicaltrials.gov with the number NCT05157022. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea, concept, design, literature review, writing the article: V.Ş.; Control, supervision: Ş.K., S.E.; Data collection and/or processing: V.Ş., Ş.K.; Analysis and/or interpretation: S.E.; Critical review: Ş.K.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding: The authors received no financial support for the research and/or authorship of this article.

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