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ORIGINAL ARTICLE

Comparison of Radial Extracorporeal Shock Wave Therapy and Traditional Physiotherapy in Rotator Cuff Calcific Tendinitis Treatment

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ABSTRACT

Objectives: This study aims to investigate the efficacy of radial extracorporeal shock wave therapy (rESWT) in relieving pain and improving range of motion (ROM) and functionality besides conventional physiotherapy methods in the treatment of chronic rotator cuff calcific tendinitis (RCCT).

Patients and methods: We studied 80 patients (35 males, 45 females; mean age 53.3±9.6 years; range, 40 to 70 years) with chronic RCCT. Patients were randomly divided into two groups: rESWT group (n=40) treated with conventional physiotherapy and rESWT, and control group (n=40) treated only with a conventional physiotherapy program. The traditional physiotherapy program included ultrasound, transcutaneous electrical nerve stimulation, shoulder joint ROM and stretching exercises, and ice applications. All patients received a total of 20 treatments, five days a week for four weeks. rESWT was applied once a week for four weeks in total. Before and after treatment, all patients were evaluated for age, height, weight, body mass index (BMI), pain intensity with a visual analog scale, shoulder ROM, and functional disability status with the shortened version of the Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH).

Results: Mean BMI value of the participants was 26.1±3.0 kg/m^2. Although all parameters of the patients in both groups improved significantly, patients in the rESWT group had a statistically significant improvement in pain, ROM and QuickDash scores ($p<0.001$, $p<0.001$, and $p<0.001$, respectively).

Conclusion: We assume that rESWT is an effective and noninvasive method of reducing pain and increasing ROM and functional status without the need for surgery.

Keywords: Extracorporeal shock wave therapy; fibromyalgia; rheumatoid arthritis; rotator cuff tendinitis.

Calcific tendinitis of the shoulder is a common disease of the rotator cuff muscles causing pain and decreased range of motion (ROM). The disease mainly affects individuals aged 30-60 years. Males and females are equally affected. The calcific material consists of a collection of calcium hydroxyapatite in crystalline or amorphous form.[1,2] Approximately 80% the calcium deposits are located in the supraspinatus tendon, 15% in the infraspinatus tendon, and approximately 5% in the subscapularis tendon. In the supraspinatus tendon, the most affected location is 1.5 to 2.0 cm away from its insertion at the greater tuberosity. The etiology of the calcium deposition in the rotator cuff is disputable.[3,4] It has been suggested that it was related with decreased local oxygen pressure or hypoxia. The prevalence of calcification in the rotator cuff has been reported to be between 2% and 20% in asymptomatic shoulder joints. The reported prevalence in patients with shoulder pain is up to 50%.[5]

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The traditional treatment of calcifying tendinitis of the shoulder is based on many therapies including administration of analgesics and anti-inflammatory drugs, local steroid injections, lavage, needling, physiotherapy as well as surgical or arthroscopic removal of the calcific deposit. There are various opinions about the most effective method in the treatment of calcific tendinitis, but studies on the efficacy of extracorporeal shock wave therapy (ESWT) are also available.[6]

Shock wave therapy is an effective method of dissolving calcification and stimulating tissue healing.[7,8] Extracorporeal shock wave therapy is a treatment method in which high-amplitude sound waves are focused on the desired part of the body. This method was used in 1970s for destruction of kidney and bile duct stones. The use of this method has become widespread in various musculoskeletal disorders including tendinopathy, enthesopathy, and calcifications.[9] In the past few years, orthopedic research studies on the treatment of tendon diseases, such as enthesopathy, calcaneal spur, tennis elbow, and calcifying tendinitis of the shoulder, have been performed. Discordant results have been reported with respect to the efficacy of ESWT in the treatment of chronic calcifying tendinitis of the shoulder.

The mechanism of shock wave therapy is not fully understood. ESWT has been used in the treatment of various musculoskeletal conditions, including tendinopathies and enthesopathies, at doses of 10 to 20% of those used in lithotripsy for renal stones. The most important physical parameters of shock wave therapy in the treatment of orthopedic diseases are pressure distribution, energy flux density, and the total acoustic energy. Unlike the shock wave that is used to break up renal stones, it is used in the treatment of musculoskeletal disorders to cause interstitial and extracellular responses, and tissue regeneration. Theoretically, the benefits are tissue healing and breakdown of calcification. Although ESWT is routinely used for the treatment of urolithiasis, it has received acceptance in European countries for treating musculoskeletal conditions and there have been few clinical controlled studies in the United States regarding its use in some musculoskeletal diseases.[9,10]

In this study, we aimed to investigate the efficacy of radial ESWT (rESWT) in relieving pain and improving ROM and functionality besides conventional physiotherapy methods in the treatment of patients with chronic rotator cuff calcific tendinitis (RCCT).

PATIENTS AND METHODS

This study was conducted between August 2017 and April 2018 at Istanbul Bilgi University Faculty of Health Sciences and included 80 patients (35 males, 45 females; mean age 53.3±9.6 years; range, 40 to 70 years) who received a diagnosis of chronic RCCT in different centers. The criteria for inclusion were a minimum of 12 months of shoulder pain (a period of time enough for considering a chronic pathology that is resistant to other treatments) as well as calcification of the rotator cuff and age between 30 and 70 years. Exclusion criteria were local or generalized arthritis (excluded by clinical examination), algodystrophy, pregnancy, acute infection, skin ulcerations, neurological abnormalities, dysfunction in the neck or thoracic region or both, acute (severely painful) calcific shoulder tendinopathies, a history of previous surgery or malignancy, corticosteroid injection within the preceding six months, or previous ESWT treatment. The study protocol was approved by the Istanbul Bilgi University Faculty Ethics Committee. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients were randomly divided into two groups. A list of computer-generated random numbers was provided by one of the investigators. rESWT group (n=40) was treated with conventional physiotherapy and rESWT, while control group (n=40) received conventional physiotherapy only. The traditional physiotherapy program included ultrasound (1.0 MHz, 5 minutes, continuous), transcutaneous electrical nerve stimulation (conventional, 20 minutes), shoulder joint ROM and stretching exercises, and ice applications (15 minutes). The physiotherapy program was applied five days a week for four weeks. rESWT was conducted using a ShockMaster 500 device (GymnaUniphy NV, Bilzen, Belgium) once a week for four weeks in total. Each treatment consisted

of 1,500 shocks with a frequency of 150 shocks per minute. The dimensions of the focal zone were 5.5 mm, 5.5 mm and 35.3 mm, and the cutout was 95 mm. When minimal energy was generated, the flux density was calculated to be 1.23 mJ and the total energy to be 2.59 mJ. The energy at 5 MPa was 1.77 mJ and 4.03 mJ, the focal region was 0.91 mJ at 5 mm and 1.91 mJ. Since pain could occur mostly during the first treatment, all patients were treated with a low energy density of 0.03 mJ/mm^2 for the first five minutes, which was then progressively increased to 0.28 mJ/mm^2. Each rESWT session took about 10 minutes. rESWT application was performed on the supraspinatus, infraspinatus, teres minor, and subscapularis tendons. In successive treatments, an energy density of 0.28 mJ/mm^2 was used. The maximum energy flux density did not exceed 0.28 mJ/mm^2, taking into account the patient's level of tolerance. An isotonic gel was used as an intermediate before the probe was applied to the patient's shoulder, and no local anesthetic was used. The application was carried out without any anesthesia in order to better localize the area to be treated and to detect the amount of energy used in the patient. The rESWT procedure was performed by positioning the patient at the internal and external rotations at a maximum of 15 degrees with the patient in an upright sitting position. The patients were sufficiently informed on the nature of the treatment and its consequences. After applying a transparent and odorless gel on the skin that facilitates the spread of the waves to biological tissues, the generator's head was positioned under ultrasound guidance to focus on the shock waves in the target area. Before and after treatment, all patients were evaluated for age, height, weight, body mass index (BMI), pain intensity assessed using a Visual Analog Scale, shoulder flexion, extension, abduction, external rotation ROM with goniometer, and functional disability status with the shortened version of the Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH).

Upper extremity functional assessment was performed with the QuickDASH, which is a regional outcome measure evaluating the entire upper extremity function developed for upper extremity musculoskeletal system disorders and scored in two components: the disability/symptom section (11 items) and the optional high performance sport/music or work modules (four items). Each item is rated on a five-point Likert-type scale and the total cumulative score is scaled from 0 to 100 with higher scores indicating more disability. The Turkish version of the scale has been validated.[11] Completion time is about three-four minutes and the ease of scoring is moderate. The total cumulative score was obtained by adding up the assigned values for each response and dividing by the number of items by the number of marked items and subtracting 1, and multiplying the resulting score by 25.[12]

Statistical analysis

The IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA) was used for statistical analyses. This analysis revealed a standard effect size of 0.72 and at least 80 cases with a 95% confidence interval and a power of 80%. In order to assess the difference between the groups, the Mann-Whitney U test was used in continuous data which were independent from each other among the groups. The Wilcoxon test was used to assess the pre- and post-treatment variables. A p value lower than 0.05 was considered statistically significant.

RESULTS

Mean BMI of the participants was 26.1±3.0 kg/m^2. Sociodemographic variables were given in Table 1. There was no statistically

Table 1. Demographic characteristics of patients

	rESWT Group (n=40)	Control Group (n=40)		
	Mean±SD	Mean±SD	z	p
Age (year)	54.33±9.88	51.31±8.86	-1.126	0.260
Body mass index (kg/m^2)	28.29±0.47	25.50±3.11	-1.884	0.060

rESWT: Radial extracorporeal shock wave therapy; SD: Standard deviation; Mann-Whitney U test.

Table 2. Inter- and intragroup comparisons of pain, range of motion, and shortened version of Disabilities of Arm, Shoulder and Hand questionnaire score

	rESWT Group	Control Group		
	Mean±SD	Mean±SD	z	p
Visual analog scale 1	7.4±0.8	7.3±0.9	-0.139	0.890
Visual analog scale 2	1.3±0.7	2.5±1.0	-4.617	<0.001**‡
z	-5.408	-3.886		
p	<0.001**†	<0.001**†		
Range of motion flexion 1	133.5±18.9	135.9±20.2	-0.524	0.601
Range of motion flexion 2	171.1±8.4	139.5±22.9	-4.739	<0.001**‡
z	-5.164	-2.207		
p	<0.001**†	0.027*		
Range of motion extension 1	17.1±6.9	14.9±7.1	-1.149	0.250
Range of motion extension 2	33.8±6.3	16.8±6.9	-5.538	<0.001**‡
z	-5.251	-2.675		
p	<0.001**†	0.007†		
Range of motion abduction 1	115.8±21.8	120.1±28.8	-0.709	0.478
Range of motion abduction 2	167.0±9.4	125.2±27.5	-5.294	<0.001**‡
z	-5.233	-3.685		
p	<0.001**†	<0.001**†		
Range of motion external rotation 1	25.8±16.9	23.0±17.2	-0.639	0.639
Range of motion external rotation 2	49.0±12.5	25.8±15.7	-4.337	<0.001**‡
z	-4.376	-2.911		
p	<0.001**†	0.004†		
QuickDASH 1	24.0±23.0	13.3±11.0	-1.081	0.280
QuickDASH 2	1.3±1.8	12.6±11.0	-3.556	<0.001**‡
z	-3.181	-2.023		
p	<0.001**†	0.043*		

rESWT: Radial extracorporeal shock wave therapy; SD: Standard deviation; 1: Pretreatment; 2: Posttreatment; QuickDASH: Shortened Version of Disabilities of the Arm, Shoulder and Hand questionnaire; * p<0.05; ** p<0.001; † Wilcoxon test; ‡ Mann-Whitney U test.

significant difference in terms of age or BMI between the groups (p>0.05).

Although all evaluation parameters improved significantly in both groups, patients in the rESWT group had a statistically significant improvement in pain and ROM (p<0.001 and p<0.001, respectively) (Table 2).

A review of the QuickDASH scores of our patients demonstrated moderate functional limitations before treatment and increased functional status after treatment in all patients, while overall functional status was fully improved in patients of the rESWT group (p<0.001) (Table 2).

DISCUSSION

Rotator cuff calcific tendinitis is a common disabling condition, often chronic and recurring. It is a leading cause of shoulder pain with a prevalence of 5-39% in the general population.[13] ESWT is an effective treatment modality that reduces pain and increases function, particularly in chronic tendon injuries of the shoulder.[14] RCCT is most common among people between 30 and 60 years of age.[15] The mean age of the patients in our study was 53.3±9.6 years. When we evaluated the relationship between BMI and RCCT, it was seen that obesity was a risk factor for RCCT development. In their study including 311 patients aged 53-77 years, who underwent rotator cuff repair, arthroscopy, and/or other procedures of the repair of the shoulder between 1992 and 2000, Wendelboe et al.[16] reported that increasing BMI was a risk factor for rotator cuff tendinitis and related conditions. The mean BMI of patients in our study was 26.1±3.0 kg/m^2.

The limited response to most conservative measures has led to the development of new forms of treatment. In the treatment of rotator cuff, various medical treatments, injection, physiotherapy agents, and surgical methods are used.[17] Although conservative methods are

preferred for the treatment of RCCT, surgical methods are applied in cases not showing clinical improvement with physiotherapy for over six weeks. Physical therapy methods are beneficial for soft tissue healing, reduction of calcification, and inhibition of pain receptors.[1,18,19] We assume that patients with RCCT may be treated with ESWT, a non-invasive method, without surgical intervention.

Shock wave treatment is increasingly used for rotator cuff pain. Since 1992, ESWT has been used in the treatment of pain, enthesopathy in particular.[20] The mechanism of action of ESWT is not fully known. It has been shown that increasing the diffusion of cytokines from the vessels leads to angiogenesis and neovascularization in the tendon-bone region.[15] By stimulating cerebral cortex with serotonergic activation from the dorsal root, the descending pathways are thought to enhance inhibitor control and provide hyperstimulation analgesia. ESWT also affects pain by reducing calcitonin gene-related protein production from the dorsal root. It has been reported that ESWT does not cause damage to the joint cartilage and there is no thermal effect. The effect also depends on the amount of energy applied to the tissue.[15] There have been studies reporting that ESWT was effective in reducing pain in patients with RCCT involving impulses delivering 0.28-0.45 mJ/mm^2.[3,15,21] In their study evaluating an individualized rESWT protocol for the treatment of symptomatic calcific shoulder tendinopathy, Malliaropoulos et al.[22] found a success rate of 92% at 12-month follow-up, 52% reduction in mean VAS immediately posttreatment, 62% at one month and 75% at three months. This improvement in symptoms was maintained at one year with an 88% mean VAS reduction from baseline at 12 months and only 7% recurrence rate (mean pretreatment VAS of 4.7 decreased to a mean posttreatment VAS of 2.4 (six-month follow-up).

It has been shown that conservative treatment for calcific tendinitis of the shoulder provided a significant improvement regardless of the location, type, size, and initial symptoms of calcific deposits.[23] Chou et al.[24] reported that of 241 shoulders with symptomatic RCCT treated with ESWT, complete resorption and incomplete resorption of calcification were observed in 134 and 107 shoulders, respectively. The symptom free rate was 81% in shoulders with complete resorption and 23.4% in those with incomplete resorption. Our study also showed a 14.28% reduction in pain in patients treated with rESWT.

Extracorporeal shock wave therapy has been suggested to be an alternative method of treatment for calcific and non-calcific rotator cuff tendinitis that would decrease the need for surgery.[25] Huisstede et al.[17] evaluated 17 studies on the efficacy of ESWT application in rotator cuff tendinitis. Eleven of these were RCCT and six were non-RCCT. At the end of their study, they reached evidence that ESWT was more effective than placebo and other treatment modalities in the treatment of RCCT, but not in non-calcified tendinitis.[26] There are various viewpoints on the influence mechanisms of ESWT. Perlick et al.[27] assumed that the mechanism of the shock waves was not due to physical defragmentation of the calcification, but was due to the inflammatory changes at the trigger points as a result of the mechanical irritation of the shock waves. The success rate of shock wave therapy in patients with calcific tendinitis of the shoulder has been reported to range from 78 to 91%.[28-33] Wang et al.[34] compared the results of shock wave therapy in 37 patients (39 shoulders) with calcific tendinitis of the shoulder with a control group of six patients (six shoulders). At two- to three-year follow-up, the overall results of the shock wave group were complaint-free in 60.6%, significantly better in 30.3%, slightly better in 3.0%, and unchanged in 6.1%.[34] Wang et al.[35] reported that shock waves led to an increase in the blood flow in the focused tissue and stimulated recovery. On the other hand, Rompe et al.[5] reported that surgery was superior compared to high-energy ESWT for patients with calcific tendinitis of the shoulder with homogenous deposits while high-energy ESWT was equivalent to surgery for those with homogenous deposits. Our study also showed a 28% increase in shoulder flexion, 44% increase in shoulder abduction, 94% increase in shoulder extension, and 96% increase in shoulder external rotation. In addition, no adverse events associated with high-energy impulse were observed in patients treated with ESWT.

In their systematic review and meta-analysis, Steuri et al.[36] reported that ESWT was more

effective in improving function, pain, and active ROM than sham ESWT. It has been shown that ESWT at a dose of equal to and over 0.28 mJ/mm^2 was more effective in improving shoulder functions and reducing pain.[37] In our study, patients treated with ESWT had a 43% improvement in shoulder functional status compared to controls.

This study has several limitations. The patients were evaluated twice at the beginning of treatment and at the end of treatment; however, long-term follow-up was not performed to assess the success of therapy. In addition, the success of treatment was not evaluated via imaging techniques in terms of the location and amount of calcification, but assessed with regards to shoulder pain, range of motion, and functionality.

In conclusion, we may suggest that rESWT is a non-invasive and effective method of treatment for RCCT providing early pain reduction and improved ROM, and functional status.

Declaration of conflicting interests

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