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Research Paper

The effectiveness of extracorporeal shock wave therapy (ESWT) on patients with rotator cuff syndrome

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Abstract

Aim: The aim of this research is to investigate the effectiveness of ESWT (Extracorporeal Shock Wave Therapy) on patients diagnosed with RCS (Rotator Cuff Syndrome) along with physical therapy.

Data and Methodology: In this study, 60 patients were randomly divided into two groups of equal sizes. The first group was treated with 5 minutes of Ultrasound, 30 minutes of TENS and 20 minutes of hot-packs 5 days a week for 3 weeks. For the second group, ESWT was applied for a total of 6 sessions 2 days a week in addition to the above treatments. Constant and UCLA scores and the (Short-Form Health Survey) SF-36 quality of life scale were used in the assessments. The joint range of motion was measured with a goniometer and the strength parameter was measured with a strength measuring device.

Findings: In a constant measurement of the patients, sleep and abduction parameters showed a significant difference at the end of the treatment compared to the pre-treatment values. For those parameters, which differed significantly, the difference before and after the treatment was significantly higher for the ESWT (+) group than the ESWT (-) group. Sleep, abduction and flexion parameters displayed a significant difference in the third-month assessments compared to the pre-treatment values. For those parameters which showed significant differences, the pre-treatment and third-month change with the ESWT (+) group were significantly higher than that with the ESWT (-) group.

Conclusion: It was found that ESWT positively improved parameters such as pain, sleep, daily life activities, active range of motion and muscle strength in conservative treatments of Rotator Cuff Syndrome (RCS). Therefore, it is concluded that ESWT is an effective and safe method that can be used in addition to physical therapy.

Keywords: rotator cuff, extracorporeal shock wave therapy, subacromial impingement syndrome, physical therapy
Abbreviations: ESWT: Extracorporeal Shock Wave Therapy; RCS: Rotator Cuff Syndrome; TENS: Transcutaneous Electrical Nerve Stimulation; SIS: Subacromial Impingement Syndrome; UCLA: University of California at Los Angeles

INTRODUCTION

Back Rotator cuff lesions are the most common cause of shoulder pain and may lead to a variety of conditions ranging from Subacromial Impingement Syndrome (SIS) and rotator cuff tendinitis to partial or full-thickness tears [1]. The main pathology in rotator cuff lesions is the impingement of the tendons of the muscles forming the rotator cuff in the subacromial space and the coracoacromial arch. As a result of a narrowing of the subacromial space, the rotator cuff is squeezed between the humeral head and acromial arch due to abduction and anterior flexion of the arm and the result is inflammation. Degenerative tendonitis and rotator cuff tears develop after recurrent impingement and inflammation attacks [2].

In general, shoulder problems such as rotator cuff tendinitis, partial tears, and subacromial impingement can be treated conservatively and surgically. Conservative treatments include physical therapy modalities (hot packs/cold packs, infrared, ultrasound, analgesic currents, electrical stimulation, laser, and ESWT), kinesi taping and exercises, and joint injections.

Of these forms of physical therapy, ESWT is a non-invasive treatment based on strong sound waves focusing on a specific part of the body by means of an ellipsoidal head. Its primary biological effects include pain relief, tissue regeneration and calcification destruction [3].

ESWT has been used as an alternative treatment for calcific tendinitis of the shoulder since 1993. In addition, ESWT has been used in the treatment of many conditions such as tendinopathies, bone fracture healing, delayed or failed bone union, calcific tendinitis of the shoulder, lateral epicondylitis, and plantar fasciitis, and the results have been satisfactory.

Rotator cuff pathologies are associated with pain during shoulder elevation and external rotation movements as well as decreased shoulder movement and functions. Genetic and hormonal effects, lifestyle factors such as smoking and alcohol consumption, anatomical pathologies, peripheral and central sensitization, sensory-motor changes and psychosocial factors contribute to the formation of rotator cuff pathologies; however, excessive and incompatible loads on tissues is considered to be the most important factor.

A significant cause of shoulder pain is the rotator cuff, and the primary factors are tendon disorder symptoms of various types [1]. While there is a lack of consensus concerning the origin of degeneration in the rotator cuff, many factors are thought to cause it [4]. Such degeneration of the rotator cuff is generally analyzed by dividing it into two categories: extrinsic [5,6] and intrinsic [6-8].

EXTRINSIC MECHANISM

There is disagreement about the origin of pathologies emerging from the extrinsic mechanism. According to Neer, 95% of these pathologies occur as a result of irritation of the subacromial bursa and rotator cuff tendons [1,9]. The pathology referred to as subacromial impingement syndrome is marked by changes in the anterior part of the lower surface of the acromion, ligaments and sometimes in the acromioclavicular joint [4]. According to Morrison and Bigliani [10], changes in the acromion are associated with tears. In an examination of 140 cadavers of persons who were older than 70 years of age, full-thickness tears were found in one-third of the shoulders. Type III acromion was observed in 73% of the shoulders with a tear, Type II in 24% and Type I in 3%. Putz and Reichelt [11], on the other hand, analyzed 133 patients and found chondroid metaplasia at the junction of the coracoacromial ligament with the acromion in 75% of patients [12].

INTRINSIC MECHANISM

As posited by Codman, the intrinsic mechanism explains the causes of rotator cuff tears with degenerative changes [13]. This explanation has been adopted by many researchers and it has been suggested on this

basis that rotator cuff tears are formed by the joint. Studies have shown that extrinsic mechanisms only have a secondary effect [14].

There may be losses in the normal organization of the bones, fibrocartilage, and tendons in the rotator cuff. In cadaveric studies, decreased vascularization was observed in the anterior supraspinatus tendon. This hypovascular region corresponds to the critical area described by Codman in intrinsic mechanisms [13]. The fact that a significant amount of degeneration causing rotator cuff tears taking place in this critical area has led to the possibility that hypo vascularity affects tear formation.

In another study, on the other hand, Swiontkowski et al. [15] tried to determine whether there was any flow in the critical area of the normal tendon by using doppler, and they found an increased amount of flow in torn tendon edges. Pressure studies on subacromial distance show that lifting a load of 1 kg above the shoulder causes an increase in pressure to the extent that it prevents microcirculation [16].

It has also been found that the rotator cuff changes with age. In a study on this issue, Brewer [17] detected a decrease in fibrocartilage at the adhesion site of the cuff and at the same time observed deterioration in vascularity, cellular losses and tendon fragmentation. In this regard, it can be seen that rotator cuff tears may occur in various ways.

CALCIFIC TENDINITIS

Calcific tendinitis can be a cause of shoulder pain. Soft tissue calcification in the shoulder region usually occurs on the bursal side of the glenohumeral joint, most often on the bursal side of the area where the supraspinatus tendon adheres to the tuberculum majus. The formation of calcific tendinitis is dependent on the storage of hydroxyapatite and calcium pyrophosphate.

Since most of these lesions disappear spontaneously after phagocytic resorption, conservative methods are the first choice in treatment. Nevertheless, symptoms of certain cases can become chronic.

Subacromial Impingement Syndrome (SIS) is a commonly used term to describe rotator cuff pathology [18,19] and it has been observed in approximately 60-70% of patients with shoulder pain [20]. According to Neer, SIS can be categorized into two groups: outlet and non-outlet [9,21].

TREATMENT

Conservative and surgical therapies are used for the treatment of rotator cuff lesions. The main purpose of conservative therapy is to regain normal shoulder functions, and this type of therapy includes many treatment components. Based on numerous activities such as patient education, physical therapy modalities, strengthening, techniques for increasing motor control, and stretching and mobilization exercises, conservative therapies are used to restore the normal balance of the muscles around the shoulder [22]. Patient education includes informing the patient about the syndrome, how to use the painful shoulder in the activities of daily life and also the effectiveness of the treatment modalities. One of the physical therapy modalities, ESWT, has been widely used in the treatment of musculoskeletal disorders in recent years, sometimes as the first choice and sometimes as supportive treatment.

ESWT

ESWT is a treatment method that involves applying high-intensity pressure waves to the body [23]. Shock wave therapy has been used in the field of urology since the 1980s and it has recently been developed for use in the treatment of musculoskeletal disorders. In fact, shock wave therapy has recently been prioritized in treating musculoskeletal disorders. This therapy is also used sometimes as the first choice and sometimes as supportive treatment of plantar fasciitis, calcaneal spurs, lateral epicondylitis, and calcific tendinitis of the shoulder. In 2000, the American Food and Drug Administration (FDA) authorized use of this

therapy for various diseases, and clinical evidence suggests that it can be used in the treatment of certain conditions. Hence, it is possible that this method may be used more widely in the near future.

Shock waves are short, single, high amplitude pulsatile acoustic waves. They function by dissipating their mechanical energy in two different tissues which have two different acoustic impedances. Shock waves are produced by a generator and applied to the body area with a focuser. The slippery gel is used to facilitate the passage of shock waves formed in water and similar liquid media into tissues [24-26].

However, the effect mechanism of ESWT is not fully known. According to the findings of studies on the subject, it stimulates angiogenesis by increasing the diffusion of cytokine in vessels. It may also function by creating neovascularization in the tendon-bone region. In addition, shock waves are thought to stimulate the brainstem via dorsal root serotonergic activation and increase inhibitory control and also lead to hyperstimulation analgesia. Studies have shown that ESWT does not cause any changes in joint cartilage and does not create any thermal effects [27].

In the use of ESWT, it is necessary to correctly determine the body area to which to apply it. Three different methods can be utilized: Anatomical focus, focusing via imaging methods and clinical focus. In anatomical focus, the area of application (the body region to be treated) is determined by palpation. As imaging methods, ultrasound, fluoroscopy or computed tomography can be used to focus on the application area. The third method is clinical focus. With this method, an application is made after asking the patient about the location of pain. It is a reliable approach, but anesthesia should not be used with this method [28].

ESWT is used to treat many conditions including bone fracture union, stress fractures, avascular bone necrosis, osteochondritis dissecans, osteoarthritis, trochanteric pain syndrome, calcific tendinitis, lateral epicondylitis, medial epicondylitis, plantar fasciitis and tendinopathies, Peyronie's Disease, chronic pelvic pain syndrome, wound healing, spasticity, myocardial ischemia and periodontal diseases.

The use of ESWT, however, causes contraindications in situations with malignant conditions, blood coagulation disorders, pathological-neurological conditions, pregnancy, active infection and cardiac pacemaker use [29].

Furthermore, ESWT can lead to numerous complications when applied in large dosages. For this reason, monitoring should be carried out during application of the treatment. A common approach with this treatment is to administer small dosages [27]. The main complications include skin erythema, pain, feeling ill, sensitivity, petechia, hematoma and hemorrhaging, edema, migraine attacks and nausea [30].

ESWT TREATMENT FOR CALCIFIC TENDINITIS OF THE SHOULDER

In the chronic or subacute stage of calcific tendinitis, various treatments can be applied, especially physical and local anesthetic treatments. The success rate of conservative treatments varies between 30%-85% [31]. There are clinical and experimental findings showing that ESWT has yielded successful results in recent years. However, there is no consensus on the effect mechanism of this treatment. According to Loew et al. [32], as pressure increases in the shock wave focus, calcific deposits are dissolved and absorbed by the surrounding tissues. Perlick et al. [33], on the other hand, suggest that the triggering of the inflammatory change caused by irritation in the tissues by shock waves is effective in this dissolution of calcification. In opposition to these opinions, another researcher [25] points to the effect of increased blood circulation.

DATA AND METHODOLOGY

This study included patients aged between 21 and 65 with their

full cooperation. They had been admitted to the Physical Therapy and Rehabilitation Clinic of Medical Park Fatih Hospital between 2015 and 2016 for shoulder pain complaints and diagnosed with rotator cuff syndrome. Patients with malignant conditions, systemic and neurological indications, pregnant women, patients with active infections, patients with implanted devices such as pacemakers, and total tears of the rotator cuff were excluded from the study.

The individuals participating in the study were informed about the study's purpose and duration, as well as the evaluations and questionnaires involved. They read and signed a volunteer information and approval form.

60 patients who met the criteria for participation in the study were randomly divided into two groups according to their order of arrival.

For the first group 1.2 W/cm² and 2 MHz Ultrasound for 5 minutes; 30 minutes TENS which has an amplitude of 120 mA, frequency of 10 Hz and pulses of 200 µs; and 20 minutes of hot-packs were applied 5 days a week for 3 weeks and they took part in an exercise program. In the second group 6 sessions ESWT for 1.6 bars and 0.11 mJ/mm² were applied twice a week in addition to the above treatments. Assessments were made before, immediately after and 3 months following the treatment.

Constant and UCLA scores and SF-36 quality of life scale were used to evaluate the patients. In addition, constant and UCLA scores were used for evaluations of shoulder function. In these evaluations, the joint range of motion was measured with a goniometer, and muscle strength was measured with a strength measuring device. Shoulder flexion muscle strength was evaluated with a manual muscle test.

The demographic data obtained from the patients included in the study and the measurement results obtained before, immediately after and 3 months after the treatment. SPSS for windows version 20.0 was used for the analyses.

FINDINGS

Of the patients included in the study, 39 were male (65%) and 21 were female (35%). 11.7% of the patients were aged between 27 and 35, 48.3% were aged between 36 and 45, and 40% were 46 and older. All of the patients were evaluated 3 times before, immediately after and 3 months after the treatment.

In the ESWT (+) and ESWT (-) groups, none of the Constant and UCLA scores and SF-36 quality of life assessments differed significantly before the treatment ($p > 0.05$) (Tables 1-3).

The results for the two groups are as follows:

In the constant evaluations of the patients, sleep and abduction parameters showed a significant difference at the end of the treatment compared to the pre-treatment values ($p < 0.05$). For those parameters, the difference before and after the treatment was significantly higher in the ESWT (+) group than in the ESWT (-) group. In the evaluations carried out 3 months after the treatment, the sleep, abduction and flexion parameters differed significantly between the groups. For these parameters, the pre-treatment and third-month change in the ESWT (+) group was significantly higher than the change in the ESWT (-) group.

In the ESWT (+) and ESWT (-) groups, the change in the UCLA parameters at the end of the treatment was equal to the pre-treatment level and no difference was found between the groups. In the third month evaluations, there was a significant difference between the UCLA parameters in active anterior flexion and flexion muscle strength measurements ($p < 0.05$). For the parameters which showed significant differences, the change in the ESWT (+) group was significantly higher than the ESWT (-) group.

The difference between the pre-treatment and post-treatment was not significant for any of the SF-36 quality of life parameters, nor did

Table 1. Comparison of pre-treatment constant scoring measurements by groups

Pre-treatment		n	Mean	Standard Deviation	t	p
Pain parameter (Pre-treatment)	ESWT-	30	2.67	2.54	-0.876	0.384
	ESWT+	30	3.33	3.30		
Operability (Pre-treatment)	ESWT-	30	2.13	1.04	0.823	0.414
	ESWT+	30	1.93	0.83		
Entertainment/Sports (Pre-treatment)	ESWT-	30	1.40	1.30	-0.468	0.642
	ESWT+	30	1.53	0.86		
Sleeping (Pre-treatment)	ESWT-	30	0.90	0.80	1.520	0.134
	ESWT+	30	0.60	0.72		
Level of hand usability (Pre-treatment)	ESWT-	30	7.60	1.10	-0.668	0.507
	ESWT+	30	7.80	1.21		
Abduction (Pre-treatment)	ESWT-	30	8.13	1.74	0.860	0.393
	ESWT+	30	7.67	2.41		
Flexion (Pre-treatment)	ESWT-	30	8.67	1.32	1.526	0.132
	ESWT+	30	8.07	1.70		
Internal rotation (Pre-treatment)	ESWT-	30	5.80	2.06	-1.363	0.178
	ESWT+	30	6.47	1.72		
External rotation (Pre-treatment)	ESWT-	30	6.00	1.74	0.235	0.815
	ESWT+	30	5.87	2.57		
Strength parameter (Pre-treatment)	ESWT-	30	13.53	3.21	-1.129	0.264
	ESWT+	30	14.47	3.19		

ESWT+: Higher changes after ESWT treatment; ESWT-: Lesser changes after ESWT treatment
n: n indicate the total number of subjects sampled and is equal to (n)
t: t-value measures the size of the difference relative to the variation in the sample data
p: p-value is a number between 0 and 1

Table 2. Comparison of pre-treatment UCLA scoring measurements by groups

Pre-treatment		n	Mean	Standard Deviation	t	p
Pain (Pre-treatment)	ESWT-	30	3.13	1.53	1.355	0.181
	ESWT+	30	2.63	1.33		
Function (Pre-treatment)	ESWT-	30	4.13	1.74	-1.385	0.171
	ESWT+	30	4.73	1.62		
Active anterior flexion (Pre-treatment)	ESWT-	30	4.37	0.61	0.995	0.324
	ESWT+	30	4.17	0.91		
Flexion muscle strength (Pre-treatment)	ESWT-	30	3.03	0.76	0.359	0.721
	ESWT+	30	2.97	0.67		
Patient satisfaction (Pre-treatment)	ESWT-	30	2.17	2.52	0.258	0.798
	ESWT+	30	2.00	2.49		

Table 3. Comparison of pre-treatment SF-36 quality of life assessment measures by groups

Pre-treatment		n	Mean	Standard Deviation	t	p
Physical function (Pre-treatment)	ESWT-	30	63.00	18.78	-0.456	0.650
	ESWT+	30	65.00	14.97		
Physical role difficulty (Pre-treatment)	ESWT-	30	9.17	16.39	-0.672	0.504
	ESWT+	30	12.08	17.21		
Emotional role difficulty (Pre-treatment)	ESWT-	30	13.34	16.61	-0.120	0.905
	ESWT+	30	13.89	19.12		
Energy/Vigor/Vitality (Pre-treatment)	ESWT-	30	46.33	19.69	-2.839	0.006
	ESWT+	30	60.50	18.95		
Mental health (Pre-treatment)	ESWT-	30	62.53	14.91	-0.557	0.580
	ESWT+	30	64.67	14.75		
Social functionality (Pre-treatment)	ESWT-	30	67.50	20.13	-1.901	0.062
	ESWT+	30	77.50	20.61		
Pain (Pre-treatment)	ESWT-	30	21.78	10.81	0.737	0.464
	ESWT+	30	19.87	9.23		
General health perception (Pre-treatment)	ESWT-	30	55.33	22.44	-1.188	0.240
	ESWT+	30	61.67	18.68		

they differ significantly between the ESWT (+) and ESWT (-) groups in the third month after the end of the treatment.

DISCUSSION

The rotator cuff is a complex structure consisting of the tendons of four muscles (supraspinatus, infraspinatus, subscapularis, and teres minor) that originate from the scapula and adhere to the large and small tubercles of the humerus [4].

Rotator cuff pathologies are the most common cause of shoulder pain, ranging from Subacromial Impingement Syndrome (SIS) and rotator cuff tendinitis to partial or full-thickness tears [1]. The main pathology in rotator cuff lesions is the impingement of the tendons of the muscles forming the rotator cuff in the subacromial space and the coracoacromial arch.

Neer classified rotator cuff tears according to their etiology, reporting that 95% of the tears are caused by the SIS and mostly observed in patients over 40 years of age [9,22].

Brox et al. [34] evaluated 125 patients aged between 18 and 66 who had rotator cuff pathology for at least three months.

In our study, 11.7% of the patients were aged between 27 and 35, 48.3% were aged between 36 and 45, and 40% were 46 and older. The age range of the patients included in the study was 27–65 years. The fact that the majority of the patients were over 40 years of age is consistent with the literature, but shoulder pain and rotator cuff syndrome can be observed in different age groups. However, degenerative changes in the shoulder increase with age and lead to rotator cuff syndrome.

Neer recommended non-operative treatment in all cases except massive cuff avulsion (rotator cuff tendinitis, patients with partial tears and subacromial impingement syndrome) [9].

Various studies have been carried out using certain physical therapy agents alone, combined, with placebos or comparatively in the conservative treatment of shoulder pain. One of these physical therapy agents, ESWT, is a non-invasive treatment based on the use of high amplitude sound waves focused on the body area that requires treatment [35]. Physical therapy, local anesthetics or corticosteroid injection or both can be applied in the chronic or subacute stage of calcific tendinitis of shoulder pathologies. Various studies demonstrate that the success of conservative treatment varies between 30% and 85% [31].

In the literature, the clinical success of shock wave therapy in patients with shoulder calcific tendinitis is reported to be between 36% and 85%, whereas the disappearance of calcifications radiologically is reported to be between 19% and 77%.

There are different views on the effect mechanism of ESWT in calcific tendinitis. Loew et al. [32] believe that its effect mechanism is marked by increased pressure in shock wave focus which leads to fragmentation and cavitation in calcification and ultimately dissolution in calcific deposits followed by their absorption by the surrounding tissues. Perlick et al. [33], on the other hand, argue that the effect mechanism is not due to the physical disintegration of calcification, but to the triggering of inflammatory changes as a result of mechanical irritation caused by shock waves in the tissue.

Although there no direct studies about the effects of ESWT on rotator cuff syndrome were carried out, many experimental studies have been conducted to investigate the effect of tendinopathies on a tendon-bone junction. These studies report that the possible effect mechanism of ESWT in soft tissues is the release of growth factors related to the angiogenesis associated with shock wave angiogenesis, which increases the formation of new vessels and oxygenation and accelerates tissue healing [36]. Although there are differences among studies concerning the dosage to administer and the amount of energy to be used in soft tissue pathologies, it is generally accepted that high doses cause damage and should not be administered [37].

Since there are no standardized values in the application of ESWT to body areas, low doses (1.6 bars and 11 Hz frequency) were used in our study [38,39]. It was thought that the significant changes at the end of the treatment and especially in the subsequent third month in the ESWT patient group were associated with increasing vascularization and oxygenation brought on by the effect of ESWT on angiogenesis. Wang [25] also noted that dissolution in calcification is not due to mechanical irritation but to increased blood circulation.

In our study, the rapid and positive changes in the pain and range of motion parameters of ESWT patients supported the idea that ESWT increases blood circulation, stimulates angiogenesis and increases vascularization.

In this study, although significant improvements were achieved in both groups, the results in the ESWT group were more satisfactory.

The patients included in the study were randomly divided into two groups, and the joint range of motion was found to be better in the group that did not receive ESWT treatment than the other group. As a result of the data analysis, it was thought that the positive development found in the evaluations carried out three months after the treatment for the group that did not receive ESWT may be related to this situation. The significant improvement in the physical functions of the patients brought on by a decrease in pain after the treatment in both groups suggested that it was associated with an increase in quality of life.

CONCLUSION

It is concluded that the use of ESWT in addition to physical therapy in clinics will rapidly reduce patients' complaints such as pain and insomnia, ensure a more rapid increase in joint range of motion, and consequently increase muscle strength in a short period of time, and all of these will be positively reflected in the patients' quality of life. For these reasons, it is deemed to be a method that should be tried before surgical treatment. Furthermore, ESWT is advantageous because it is less expensive than surgical treatment and enables the individual to return to work and daily activities more quickly.

As a result of this study, the rapid and significant improvement observed in the ESWT group raised the question of what the results would be like if only ESWT was utilized in conservative treatments of rotator cuff syndrome in comparison to other physical therapies. Possible significant differences revealed by such a study may well be useful in terms of time and cost, so further studies are needed in this regard.

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