Original Article

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Efficacy of Combining Extracorporeal Shock Wave Therapy and Physical Therapy in the Treatment of Rotator Cuff Tendinopathy

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Abstract:

Objective: This study aimed to evaluate the combined effectiveness of extracorporeal shockwave therapy (ESWT) and physical therapy in treating rotator cuff tendinopathy (RCT).

Material and Methods: A total of 62 patients diagnosed with RCT were enrolled in this study and randomly assigned to 2 groups. The intervention group received a treatment protocol consisting of infrared therapy, transcutaneous electrical nerve stimulation (TENS), mobilization, and active extracorporeal shockwave therapy (ESWT). The control group receives TENS, mobilization, and infrared therapy. All patients received 5 treatment sessions per week for 4 consecutive weeks, with ESWT administered once weekly. All patients were assessed for pain intensity using visual analog scales (VAS), and shoulder joint function using the Constant–Murley Shoulder Score at baseline, 2, and 4 weeks after the intervention.

Results: Although both groups exhibited significant reductions in pain intensity compared to the baseline, a statistically significant difference between the groups was observed after only 2 weeks of intervention (p-value<0.05). Furthermore, the shoulder joint function in the intervention group was significantly improved at both 2 and 4 weeks of follow-up compared to the control group (all p-value<0.05).

Conclusion: The combination of ESWT with TENS, infrared therapy, and mobilization demonstrated a superior efficacy in reducing pain in rotator cuff tendinopathy. Notably, this pain relief effect was correlated with improvements in shoulder joint function.

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Introduction

Rotator cuff (RC) tendinopathy is a progressive disorder of the RC tendons, which begins with acute tendinitis, progresses to tendinosis with degeneration and partial-thickness tears, and results in full-thickness rupture. RC tendinopathy is used to signify a combination of pain and impaired performance associated with RC tendons[1]. It is the most common cause of shoulder pain in adults[2]. Intrinsic mechanisms leading to rotator cuff tendinopathy are rotator cuff tendon mechanical properties, composition, and vascularity. Besides, extrinsic mechanisms are alterations in scapular and glenohumeral kinematics[1]. RC tendinopathy is commonly prevalent in workers, and it leads to work absenteeism and reduces productivity, seriously affecting the societal economic costs of patients[2]. The patient's daily activities and work are greatly limited in movements related to position with arms above shoulder level, carrying loads, and using vibrating tools[3,4]. Exercise and physical therapy are effective in treating rotator cuff tendinopathy [5,6]. The previous study reported that rotator cuff tendinopathy has a high incidence and recurrence rate, and symptoms often persist for about 3 years[7]. Although previous research has demonstrated that a combination of transcutaneous electrical nerve stimulation (TENS), joint mobilization, and infrared therapy is associated with significant improvements in pain control and joint function[8-11], the establishment of an effective and long-term treatment regimen for patients continues to pose a challenge in the management of rotator cuff tendinopathy.

In the late 1960s, scientists began considering the use of extracorporeal shock waves to break down internal structures like kidney stones and gallstones from outside the body without invasive procedures. In February 1980, kidney stones were successfully fragmented from outside the body using extracorporeal shock wave technology, eliminating the need for surgery. The application of extracorporeal shock waves to dissolve calcifications in the shoulder or ligaments and treat tendonitis was developed and has shown positive treatment outcomes[12,13]. Nowadays, extracorporeal shock wave therapy (ESWT) is used to treat various diseases such as Achilles tendinopathy, knee osteoarthritis, sciatic nerve injury, subacromial impingement syndrome, and chronic calcific tendonitis of the rotator cuff[14-17]. Alongside non-surgical, non-pain medication treatments, ESWT has been reported to exert various biological effects, including tissue regeneration, wound healing, angiogenesis, bone remodeling, and anti-inflammatory action. It is particularly effective in managing chronic pain and tendinopathies, and it has demonstrated promising therapeutic efficacy[12,18-20]. In recent years, although interventional methods have been assessed to determine the effectiveness of extracorporeal shock waves in treating muscle, bone, joint, and ligament conditions, the overall effectiveness of extracorporeal shock waves in these treatments remains unclear. Therefore, the aim of this study was to evaluate the efficacy of combined ESWT and physical therapy in the rehabilitation of rotator cuff tendinopathy (RCT) patients.

Material and Methods

Study design and participants

Sixty-two RCT patients took part in this study. The sample size calculation was based on the following parameters: $Z_1-\alpha/_2$ (desired statistical significance level)=1.96, d (desired absolute precision), and P (estimated ratio), which represents the proportion of good and very good outcomes after physical therapy and rehabilitation for rotator cuff tendinopathy, with p-value=0.98. With a margin of error (d) set at 0.05, the minimum required sample size was determined to be 30 per group. Thus, the minimum total sample size for both groups was 60.

$$n = \frac{Z^2_{(1-\alpha/2)} \cdot P(1-P)}{d^2}$$

Given a minimum sample size of 60 per group, we recruited 62 participants (35 males; mean age±standard deviation, 63.9±11.2 years, age range 29–90 years) to account for any possible attrition.

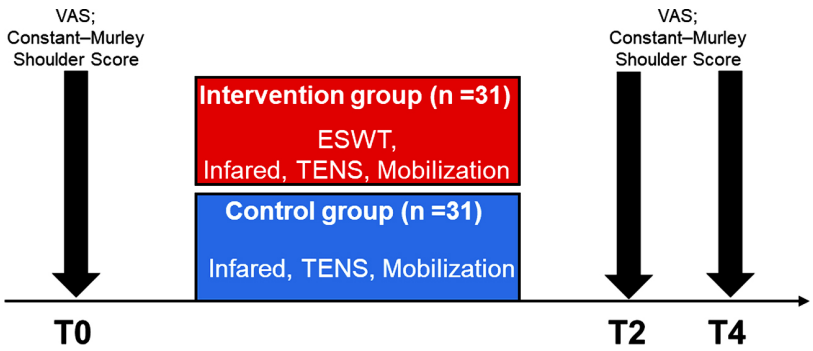
The inclusion criteria consisted of: i) patients diagnosed with rotator cuff tendinopathy, ii) patients treated at Phu Tho Provincial Hospital, and iii) patients willing to participate in the study. The exclusion criteria included: i) patients who had previously received corticosteroid injections or had skin lesions around the shoulder joint, ii) patients with blood clotting disorders, infections, tumors, or fractures in the treatment area, and iii) patients currently being treated for acute diseases. This study was approved under Decision No. 3958/QD-DHYHN, dated September 26, 2022. In addition, written informed consent was obtained from all participants.

Experimental procedure

This was a controlled prospective study. Participants were randomly assigned in a 1:1 ratio to either the intervention group or the control group. Participants were first paired based on similar characteristics, and then, within each pair, randomization was used to assign one participant to the intervention group and the other to the control group. One researcher was responsible for conducting the screening and assessments both before and after the intervention, while another researcher was assigned to randomize the participants and prescribe the corresponding exercise protocols. In the intervention group, subjects were treated by infrared (IR), TENS, mobilization, and ESWT. In the control group, subjects were treated by infrared, TENS, and mobilization. All patients in the 2 groups were treated for 4 weeks continuously, 5 sessions/week. In the intervention group, participants were treated by ESWT once/week for 5 minutes[21-25]. Pain intensity was assessed using the Visual Analog Scale (VAS), and improvement in shoulder function was evaluated using the Constant-Murley score at baseline (T0), after 2 weeks of follow-up (T2), and after 4 weeks of follow-up (T4). The experimental design is shown in Figure 1.

Physical therapy

In this study, we used IR energy (IR-2014; Yeollin Sesang – Korea) for 20 minutes of intervention. The capacity is 250W, and the distance from the bulb to the patient's skin is 50 cm. Infrared was perpendicularly illuminated on the shoulder. We used TENS with a frequency of 100Hz and an intervention time of 20 minutes[26,27]. Two electrodes



ESWT=Extracorporeal shockwave therapy

Figure 1 Study protocol

are placed around the patient's shoulder joint. Mobilization encompassed passive, active, and equipment-assisted movements, alongside manual shoulder joint stretching administered by a therapist to enhance flexibility. The objectives of these exercises were to achieve optimal ranges of flexion, extension, abduction, adduction, and rotation of the shoulder joint.

Extracorporeal shockwave therapy (ESWT)

In this study, we used the Physiotur shock machine, pressure 2 bar, frequency 10 Hz, number of pulses 2000, stimulation head diameter 15 mm (figure 2). According to the previous study[28], the patients in the intervention group received extracorporeal shock wave therapy, once/week for 4 weeks continuously (5 minutes per session). The focus probe sets were used, and in each session, patients received ESWT from anterior and posterior directions (on average, 1200 shocks between 0.1 and 0.3 mJ/mm^2), up to the maximum threshold of pain.

Clinical assessment

Visual analog scales (VAS): Pain intensity was assessed by VAS. Patients actively marked the level of pain at the time of assessment using the VAS scale. The meaning of the pain level on the scale was explained to the patients before the assessment was carried out.

Evaluation of shoulder joint function

Evaluation of shoulder joint function according to Christopher Constant and Alan H.Murley : shoulder joint function was evaluated using the Constant-Murley score (1987), with results categorized as follows, very good: 95-100 points, good: 85-94 points, fair: 75-84 points, average: 60-74 points, and poor: <60 points[29].

Statistical analysis

Statistical data analyses were performed using SPSS version 29.0 for Windows (IBM Japan Ltd, Tokyo, Japan). The normal distribution of the data was assessed using the

Figure 2 Shockwave therapy intervention

Shapiro–Wilk test. A mixed analysis of variance (ANOVA) was used to compare the change in pain intensity (VAS score) for GROUP (intervention and control groups) and TIME (T0, T2, T4). The Constant–Murley score was also analyzed using a mixed ANOVA for GROUP (intervention and control groups) and TIME (T0, T2, T4). Mauchly's test of sphericity was used to analyze the sphericity of the data obtained in each experiment. When Mauchly's test of sphericity could not be assumed, the Greenhouse–Geisser correction statistic was used. When a main effect or interaction was observed, multiple comparisons were performed using the Bonferroni method. In addition, changes in pain intensity and Constant–Murley score differences between the Intervention group and the Control group at the same time were evaluated by an independent t–test, and effect sizes were calculated using Cohen's d.

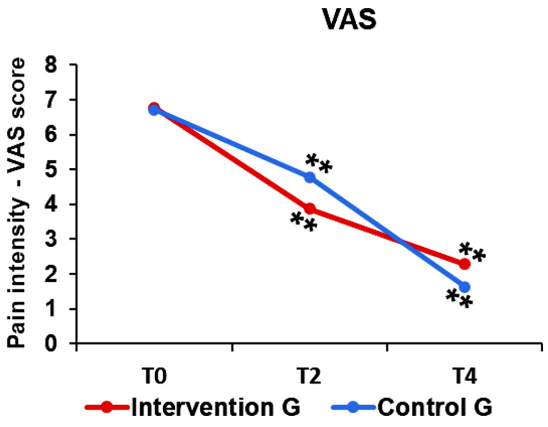
The correlation between the pain intensity and Constant–Murley score changes was assessed by Spearman's test. The level of significance was set at p–value<0.05.

Results

Pain intensity (VAS score)

T2, and T4 between the intervention group and the control group.

Figure 3 shows the changes in pain intensity before and after each conditional intervention. Mixed ANOVA was used for the GROUP and TIME factors to compare the VAS scores. The results of the mixed ANOVA revealed a statistically significant main effect of TIME [F(2, 120)=469.954, p–value<0.001, η2=0.887] and a statistically significant interaction of GROUP×TIME [F(2, 120)=3.846, p–value=0.024, η2=0.060], but no significant effect of GROUP was observed [F(1, 60)=2.132, p–value=0.149, η2=0.034]. Post hoc tests revealed significant declines in VAS scores: T2 compared with T0, T4 compared with T0, and T4 compared with T2 within both groups (all



The blue and red lines indicate the pain intensity of the control group and the intervention groups, respectively, **p–value<0.01 (vs T0)

Figure 3 Changes in pain intensity in each group

p–value<0.001). Additionally, when comparing between groups, a significant difference was detected in the VAS score at T2 (p–value=0.007). However, no significant differences were observed in the VAS scores at T0 or T4 (all p–value>0.05) (Table 2). These results indicate that pain intensity improved in both groups, with the intervention group experiencing a greater decrease in pain intensity after 2 weeks of treatment with Shockwave therapy.

Table 2 Comparison of pain intensity at T0, T2, and T4 between the intervention group and the control group

VAS (±S.D.)	Intervention group	Control group	p–value
T0	6.81±1.30	6.74±1.06	0.832
T2	3.94±1.50	4.84±1.97	0.047
T4	1.23±1.23	1.65±0.98	0.144

S.D.=standard deviation

Constant–murley score (CMS)

Figure 4 shows the changes in shoulder joint function before and after each conditional intervention. Mixed ANOVA

was used for the GROUP and TIME factors to compare the Constant-Murley scores. The results of the mixed ANOVA revealed statistically significant main effects of CONDITION [F(1, 60)= 7.055, p-value=0.01, η2=0.105] and [F(1.480, 88.817)=313.220, p-value<0.001, η2=0.839]. A statistically significant interaction of CONDITION×TIME was also observed [F(1.480, 88.817)=22.424, p-value<0.001, η2=0.272]. Post hoc tests revealed significant increases in CMS: T2 compared with T0, T4 compared with T0, and T4 compared with T2 within both groups (all p-value<0.001). Additionally, when comparing between groups, a significant difference was detected in the CMS at T2 and T4 (all p-value<0.001). However, no significant differences were observed in the VAS scores at T0 (p-value=0.798). These results show that shoulder joint function in the intervention group with shockwave therapy wassignificantly improved compared to the control group (Table 3).

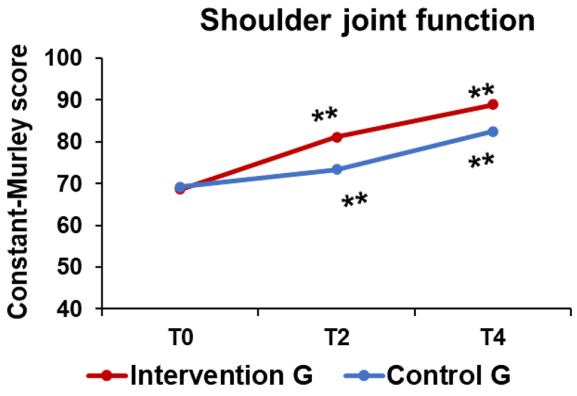
Table 3 Comparison of shoulder joint function at T0, T2, and T4 between the intervention group and the control group

Shoulder joint function (±S.D.)	Intervention group	Control group	p-value
T0	68.6±10.2	69.2±7.4	0.798
T2	81.1±7.5	73.3±6.2	<0.001
T4	88.9±6.2	82.5±5.8	<0.001

S.D.=standard daviation

The correlation of VAS and shoulder joint function

Figure 5 shows the correlation between VAS pain intensity (T0 – T2 / T0 – T4) and improvement in shoulder function, as assessed by the Constant-Murley score (T2 – T0 / T4 – T0), in both the intervention group and the control group. In the intervention group, a significant correlation was observed between the VAS score difference and shoulder functional improvement after 2 weeks of intervention



The blue and red lines indicate the shoulder joint function of the control and intervention groups, respectively, **=p-value<0.01 (vs T0)

Figure 4 Changes in pain intensity in each group

(r=0.401, p-value=0.048; Figure 5A), but not after 4 weeks (r=0.176, p-value=0.189; Figure 5B). These results suggest that shoulder function improved as pain intensity decreased within the first 2 weeks of the intervention. Conversely, in the control group, no significant correlation was found at either T0 or T2 (T0: p-value=0.692; T2: p-value=0.613; Figures 5C, D). In other words, ESWT contributed to greater improvements in shoulder joint function in the intervention group compared to the control group.

The blue circles represent the correlation between the change in rate of pain intensity and the shoulder joint function in the control group (C and D). The red circles represent the correlation between the change in rate of pain intensity and shoulder joint function in the intervention group (A and B). In the intervention group, after a 2-week intervention, there was a significant correlation between the change in rate of pain intensity and shoulder joint function efficiency (r=0.401, p-value=0.048). These results show that in the intervention group, shoulder joint function improved in individuals whose pain intensity was reduced by the combination of extracorporeal shockwave therapy and physical therapy. In other words, ESWT boosted the treatment effect in the intervention group.

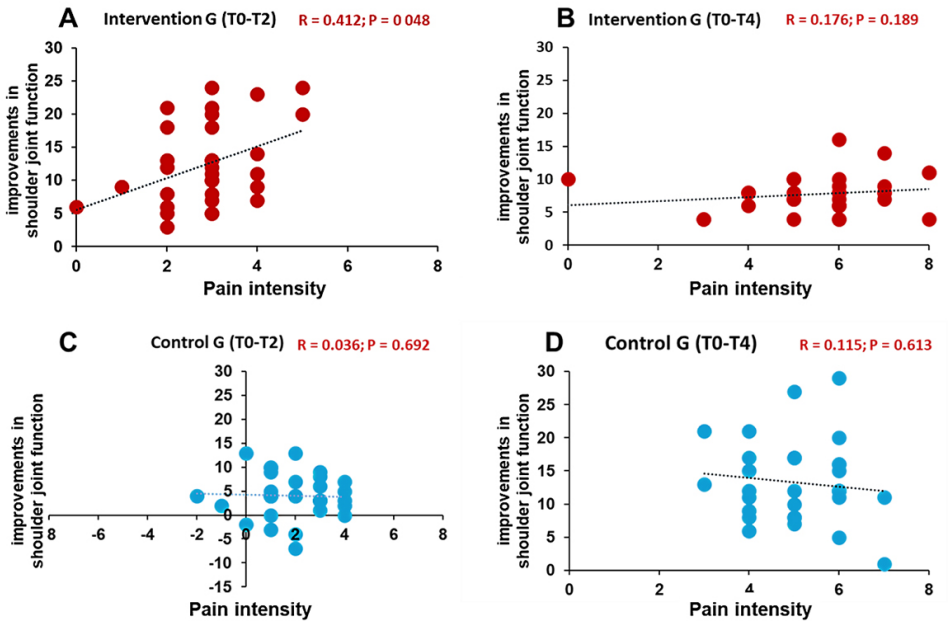


Figure 5 The correlation between pain intensity and improvements in shoulder joint function in both the intervention group and the control group

Discussion

In the present study, we examined the effectiveness of the extracorporeal shockwave therapy before and at 2 and 4 weeks of follow-up. The results showed that pain intensity in the intervention group was significantly reduced more than in the control group at the 2-week follow-up; however, this effect was not sustained at the 4-week follow-up. Furthermore, the study demonstrated that shoulder joint function in the intervention group was significantly improved more than in the control group at 2 and 4 weeks of follow-up. Conversely, this improvement was found to be associated with a pain intensity reduction in the intervention group.

In this study, although both groups exhibited significant reductions in pain intensity compared to baseline, a statistically significant difference between the groups emerged only after 2 weeks of intervention. Previous studies have shown that the combination of infrared therapy, TENS, and joint mobilization effectively reduces pain[8,10,11]. Moreover, this reduction in pain is believed to be associated with improvements in shoulder joint function in patients with rotator cuff tendinopathy[9, 11].

In terms of pain reduction, ESWT has been used in various sub-acute and chronic musculoskeletal conditions. Previous studies have used ESWT for shoulder injuries, and the results showed that ESWT can reduce pain and improve shoulder joint function[30]. ESWT increased production of prostaglandins related to the tissue repair process, increased congestion and local blood microcirculation, and increased local nitric oxide concentration with pain relief [31]. Additionally, a study by Angelo Cacchio demonstrated that ESWT induced more noticeable intermediate-term effects in the treatment of shoulder impingement syndrome[32]. Moreover, ESWT has been shown to promote tissue healing, accelerate microtrauma-induced regeneration, and enhance neovascularization[16]. In patients with rotator cuff

pathology, ESWT has been associated with a reduction in calcification size and pain[12]. Our result also demonstrated that ESWT provides additional efficacy in pain relief for patients with rotator cuff tendinopathy by producing an analgesic effect, facilitating protein synthesis and cell proliferation, and contributing to the breakdown of the pathological calcification in the tissue[33,34]. However, the results of this study showed that the difference in pain relief between groups was only significant after 2 weeks, and not at 4 weeks after the intervention. This may be related to the duration of the ESWT intervention. While the current study applied a 5-minute intervention per session, previous studies have suggested that longer durations may be more effective[13,20]. We intend to investigate this further in future research.

The results of this study also demonstrate a statistically significant correlation between pain intensity and improvement in shoulder function in the intervention group. Specifically, patients with greater pain relief tended to have better shoulder joint function. Previous studies have demonstrated that ESWT is effective in reducing pain and significantly improving joint function in patients with tendinopathy[14,17,35]. In particular, a previous study showed that shoulder joint function is strongly correlated with pain level: the higher the pain level, the greater the functional restriction of the shoulder joint[36]. Therefore, we hypothesize that the pain-relieving effect induced by ESWT may have contributed to the improved shoulder joint function observed in this study.

Conclusion

The combination of ESWT with TENS, infrared, and mobilization was shown to be more effective in controlling pain in rotator cuff tendinopathy patients than using TENS, infrared, and mobilization alone. Furthermore, a significant correlation between pain relief and shoulder joint function improvement was detected in only the intervention group.

Conflict of interest

The authors declare no conflict of interest.

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