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Clinical Study on Appropriate Energy of Extracorporeal Shock Wave for Rotator Cuff Non-calcific Tendinopathy Treatment

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Abstract

Objective: This study aims to investigate the short-term clinical efficacy of extracorporeal shock waves with different energy levels on rotator cuff non-calcific tendinopathy.

Materials and Methods: A total of 139 patients with rotator cuff rotator non-calcific tendinopathy were randomly divided into eight groups based on the different energy levels of the Dornier Aries smart focus shock wave therapy device: Level 5, 2000 shocks (0.062 mJ/mm2), Level 6, 2000 shocks (0.084 mJ/mm2), Level 7, 2000 shocks (0.096 mJ/mm2), Level 8, 2000 shocks (0.117 mJ/mm2), Level 5, 3000 shocks (0.062 mJ/mm2), Level 6, 3000 shocks (0.084 mJ/mm2), Level 7, 3000 shocks (0.096 mJ/mm2), and Level 8, 3000 shocks (0.117 mJ/mm2). Each group received shock wave treatment corresponding to the respective energy level and shock count. The visual analogue scale (VAS) and Constant-Murley score (CMS) were compared before and 1, 2, and 4 weeks after treatment to determine the short-term efficacy.

Results: The VAS scores of all groups significantly decreased at 1, 2, and 4 weeks after treatment compared to before treatment. The VAS score of the Level 7, 2000 shocks (0.096 mJ/mm2) group was significantly lower than the other groups ($P < 0.05$). The CMS scores of all groups significantly increased at 1, 2, and 4 weeks after treatment compared to before treatment. The CMS score of the Level 7, 2000 shocks (0.096 mJ/mm2) group was significantly higher than the other groups ($P < 0.05$). There was significant statistical difference in the effective rate among the eight groups ($p > 0.05$). No serious adverse reactions were observed in any group before or after the treatment.

Conclusion: Extracorporeal shock wave therapy for rotator cuff rotator non-calcific tendinopathy can alleviate shoulder joint pain, improve shoulder joint function, and enhance patients quality of life with good efficacy. The optimal therapeutic effect was observed at an energy level of 0.096 mJ/mm2 and 2000 shocks.

Keywords: Rotator cuff injury, Rotator cuff non-calcific tendinopathy, Extracorporeal shock wave therapy

Introduction

Rotator cuff tendinopathy is a common clinical condition that causes shoulder pain and restricts shoulder joint movement. It is mainly attributed to factors such as degenerative changes in the shoulder, trauma, impact, and inadequate blood supply, leading to localized pain in the shoulder joint. Due to the increasing emphasis on sports activities in recent years, the number of patients with rotator cuff injuries has also risen. The current treatment approach for rotator cuff injuries primarily involves conservative methods, including rest, massage, acupuncture, physiotherapy, functional exercises, and oral non-steroidal anti-inflammatory drugs. However, conservative treatment often yields unsatisfactory results, and symptoms are prone to recurrence. Although arthroscopic surgery for the shoulder has advantages such as small incisions and rapid postoperative recovery, the effectiveness of post-operative rehabilitation training is not ideal [1], and the procedure is not widely accepted by patients due to its high cost and susceptibility to recurrence. In recent years, with the widespread use of extracorporeal shock wave therapy (ESWT), studies by Dedes et al. [2] and others suggest that shock waves have good therapeutic effects on soft tissue injuries caused by physical activity and are beneficial for improving local function in the medium-to-long-term. Shock wave therapy has been applied in conditions such as avascular necrosis of the femoral head, Achilles tendonitis, and plantar fasciitis [3]. This study applies extracorporeal shock waves with different energy levels to treat rotator cuff non-calcific tendinopathy, observing their short-term clinical efficacy and exploring the most suitable energy level for shock wave treatment of rotator cuff non-calcific tendinopathy.

Materials And Methods

General information

The study included 139 patients who sought medical attention at the Department of Sports Medicine and Joint Surgery at Jilin Provincial People's Hospital for rotator cuff

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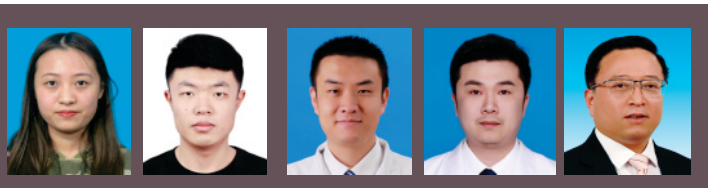

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Table 1: General information of eight patient groups

Group	Energy (mj/mm^2)	Frequency	Number	Gender		Neer Classification		Average age	Average duration
				Male	Female	I	II	(x±s, years)	(x±s, mouths)
1	0.062	2000	18	9	9	8	10	56.96±5.67	9.28±6.25
2	0.084	2000	18	11	7	12	6	57.44±6.60	9.91±3.23
3	0.096	2000	18	12	6	10	8	53.22±5.85	10.22±3.02
4	0.117	2000	17	9	8	6	11	57.06±5.75	11.06±2.63
5	0.062	3000	17	8	9	10	7	57.35±8.65	11.62±3.37
6	0.084	3000	17	10	7	5	12	53.82±6.85	10.37±3.19
7	0.096	3000	17	7	10	9	8	54.06±8.15	11.18±2.68
8	0.117	3000	17	8	9	8	9	56.65±5.70	10.47±2.66

injuries classified as Neer [4] Stage 1 and Stage 2 between September 2016 and December 2019. The ages of the patients ranged from 41 to 75 years, with a mean age of 55.82 ± 6.77 years. Among them, there were 74 male patients and 65 female patients, all with unilateral shoulder rotator cuff non-calcific tendinopathy. The duration of the conditions varied from 3 to 22 months. The patients were randomly divided into eight groups, and the basic demographic data for each group are presented in Table 1. Statistical analysis revealed no statistically significant differences among the groups in terms of gender, age, Neer classification, and duration of the condition ($P > 0.05$), indicating comparability between the groups.

Inclusion criteria

(1) Patients diagnosed with rotator cuff non-calcific tendinopathy based on physical examination and magnetic resonance imaging, and in stable general condition. (2) Meeting the diagnostic criteria for Neer Stages 1 and 2 of rotator cuff injuries, with a disease duration exceeding 3 months. (3) No prior treatment with ESWT. (4) Capable of completing ESWT treatment and follow-up as required, and not receiving alternative treatments during the period. (5) All included patients have provided informed consent.

Exclusion criteria were:

(1) Individuals with pacemakers or other implanted metallic medical devices. (2) Those with severe organ failure in the heart, lungs, or kidneys. (3) Patients with dementia or severe consciousness disorders. (4) Individuals with malignant tumors in the treatment area. (5) Patients with high fever or in the acute phase of infectious diseases. (6) Those unable to adhere to treatment or withdrew during follow-up, or had received other forms of treatment. (7) Patients with coagulation disorders. (8) Full thickness rotator cuff tears. (9) Massive rotator cuff tears. (10) Rotator cuff calcifications. (11) Glenohumeral instability.

Methods

Positioning and treatment

Patients in each group were seated with the affected limb naturally hanging down. Shockwave application points were chosen based on the Supraspinatus muscles tendon insertion point on the greater tuberosity of the humerus as a references combined with specific pain points. Coupling agent was applied to the treatment handle. A Dornier Aries smart focus shock wave therapy device was used. The handle was positioned vertically at the shock point, and shock wave treatment was administered at the corresponding energy level and pulse count. Patients were closely observed for any discomfort or adverse reactions. Treatment sessions were conducted at 1-week intervals, with a total of four consecutive treatments. Patients were instructed to maintain the same position during treatment to avoid altering the treatment site and affecting treatment effectiveness. Local cold compress was applied to the treatment point for 15 min within 3 days after each treatment, twice daily. Patients were also guided to perform passive shoulder joint functional exercises.

Observation indicators and efficacy evaluation criteria

Observation indicators

Comparison of visual analog scale (VAS) [5] and Constant-Murley score (CMS) [6] before and after treatment for each group.

Efficacy evaluation criteria

(1) VAS Score Standard: A 10 cm ruler was

Table 2: Comparison of VAS scores before and after treatment in each group (points)

Group	Before Tx	After Tx (1 week)	After Tx (2 weeks)	After Tx (4 weeks)
2000 Shocks group				
1 (18 cases)	7.06±1.21	6.33±1.14[1]	4.00±1.19[1]	2.22±1.00[1]
2 (18 cases)	7.11±1.13	6.33±1.13[1]	3.83±1.20[1]	2.21±1.03[1]
3 (18 cases)	7.06±1.39	5.94±1.31[1]	4.50±1.43[1]	1.17±1.04[1]
4 (17 cases)	7.35±1.12	5.76±1.48[1]	3.88±0.93[1]	2.12±1.17[1]
3000 shocks group				
5 (17 cases)	7.41±1.06	5.78±0.74[1]	4.00±1.12[1]	1.76±1.25[1]
6 (17 cases)	7.59±0.94	5.65±1.62[1]	3.79±0.41[1]	2.13±1.16[1]
7 (17 cases)	6.94±1.03	6.00±1.28[1]	4.06±1.20[1]	2.15±1.16[1]
8 (17 cases)	7.29±0.99	6.02±1.27[1]	3.88±1.11[1]	2.12±1.17[1]

Compared to before treatment, $^1P<0.05$; Compared to other groups, $^2P<0.05$. VAS: Visual analog scale

Table 3: Comparison of CMS scores before and after treatment in each group (points)

Group	Before Tx	After Tx (1 week)	After Tx (2 weeks)	After Tx (4 weeks)
2000 shocks group				
1 (18 cases)	59.54±6.19	72.28±4.20[1]	78.61±3.87[1]	89.33±2.06[1]
2 (18 cases)	62.00±6.45	73.56±5.11[1]	80.28±3.74[1]	89.22±2.46[1]
3 (18 cases)	61.17±4.32	69.89±3.89[1]	84.89±3.63[12]	92.22±2.67[12]
4 (17 cases)	58.82±6.10	73.94±4.78[1]	81.47±1.38[1]	89.53±1.81[1]
3000 shocks group				
5 (17 cases)	63.18±4.30	72.35±4.21[1]	81.12±1.97[1]	89.47±1.66[1]
6 (17 cases)	60.82±5.87	72.12±3.50[1]	80.59±2.60[1]	89.47±1.63[1]
7 (17 cases)	63.01±5.44	73.53±3.00[1]	80.00±2.48[1]	89.41±2.00[1]
8 (17 cases)	59.35±5.38	72.82±4.53[1]	79.24±2.73[1]	89.00±2.76[1]

Note: Compared to before treatment, $^{1}P<0.05$; Compared to other groups, $^{2}P<0.05$. CMS: Constant-murley score

used, with 0–10 cm representing scores (1 cm per point). A score of 0 indicated no pain, and 10 indicated severe pain. Patients self-evaluated the location most representative of shoulder joint pain, and the physician recorded the score. (2) CMS Score Standard: A total of 100 points, with a subjective and objective component ratio of 35/65. Components included pain (15 points), daily life activities (20 points), shoulder joint range of motion (40 points), and strength testing (25 points). (3) Short-term Efficacy Assessment Criteria: Follow-up after four treatments, with efficacy assessed based on VAS scores. Criteria were as follows:

- Significant improvement: Symptoms significantly reduced or disappeared, post-treatment pain decreased by more than 5 points, and positive signs were mostly eliminated.
- Improvement: Symptoms significantly alleviated, post-treatment pain decreased by more than 2 points, and positive signs were reduced.
- Ineffectiveness: Shoulder pain decreased by <2 points, and positive signs remained evident.

Statistical analysis

Chi-square test and analysis of variance were performed using SPSS 26.0 software.

Results

Comparison of VAS before and after treatment in each group

Before treatment, there was no statistically significant difference in VAS scores among groups ($P > 0.05$). Compared to before treatment, VAS scores in all groups significantly decreased at 1, 2, and 4 weeks after treatment, with the Level 7, 2000 shocks group showing significantly lower VAS scores than other groups ($P < 0.05$) Table 2.

Comparison of CMS before and after treatment in each group

Before treatment, there was no statistically significant difference in CMS scores among groups ($P > 0.05$). Compared to before treatment, CMS scores in all groups significantly improved at 1, 2, and 4 weeks after treatment, with the Level 7 group's CMS scores significantly superior to other groups ($P < 0.05$) Table 3.

Comparison of short-term efficacy among groups

There was statistically significant difference in the effectiveness rate among groups ($P < 0.05$), as shown in Table 4.

Comparison of adverse reactions among groups

After treatment, in Group 8, one patient experienced tachycardia and difficulty breathing. Treatment was immediately halted, and the patient was placed in a supine position for rest, resulting in symptom relief. In Group 4, one patient developed localized skin rash and mild redness at the treatment site. After rest, oral antiallergic medication, and local heat application for 48 h, the rash and redness disappeared, and treatment was successfully completed. No other significant adverse reactions were observed in the remaining groups during treatment.

Table 4: Comparison of short-term efficacy among groups (*n*)

Group	*n*	Significant improvement	Improvement	Ineffective	Efficacy rate (%)
1	18	13	2	3	83.33
2	18	13	3	2	88.89
3	18	15	2	1	94.44
4	17	13	1	3	82.35
5	17	12	1	4	76.47
6	17	13	2	2	88.24
7	17	12	3	2	88.24
8	17	11	2	4	76.47

The values in the table represent the number of cases (*n*) for each efficacy category in each group, and the efficacy rate is calculated as the percentage of the sum of "Significant improvement" and "Improvement" cases over the total number of cases

Discussion

The rotator cuff, composed of the supraspinatus, infraspinatus, subscapularis, and teres minor muscles, forms a cuff-like structure around the humeral head, controlling shoulder joint movement and maintaining stability. Rotator cuff injuries are common in orthopedic practice, characterized by degenerative changes in the muscle group, particularly prevalent in

individuals aged 50 and above [7]. The incidence increases with age [8], causing symptoms such as pain and restricted shoulder abduction, significantly affecting daily activities and quality of life. Prolonged neglect of treatment may lead to stiffness and functional impairment [9], rendering simple tasks like dressing and hair combing impossible. Patients with a duration of symptoms exceeding 3 weeks may experience varying degrees of muscle atrophy in the shoulder girdle [10]. Lack of adequate understanding in the past often resulted in misdiagnosis as shoulder periarthritis, leading to delayed treatment and worsening conditions. At present, mild rotator cuff injuries are primarily treated with methods such as manual therapy, physiotherapy, and acupuncture, but the extended treatment duration and high recurrence rates make it challenging for patients to achieve satisfactory outcomes. Surgical intervention, while effective, is often impractical for outpatient populations due to trauma and cost factors. In recent years, ESWT has gained popularity for its non-invasive approach, offering various biological effects suitable for the treatment of rotator cuff injuries. ESWT induces local mechanical effects through vibration and cavitation, causing vasodilation, aiding in tendon and soft tissue regeneration, and stabilizing local metabolism by reducing the high-frequency pulses of pain receptors and related signal transmission [11]. In addition, shock waves can suppress the function of pain receptors or peripheral nerve cells, release substance P during the process, stimulate nerves strongly, block the transmission of pain information to the cerebral cortex, and prolong post-treatment analgesia [12] by affecting the levels of free radicals around cells. Furthermore, shock waves induce minimal trauma to inflammatory tissues, promoting local microcirculation, accelerating the expulsion of inflammatory substances, and increasing pain thresholds to alleviate pain. ESWT can also improve the local environment and metabolism by promoting the expression of vascular growth factors, facilitating pain relief and tissue repair.

As an emerging treatment for rotator cuff injuries, ESWT requires continuous exploration and research for improvement. Parameters such as treatment dosage and shock wave frequency and number of pulses need further clarification. The "Chinese Guideline for ESWT in Musculoskeletal Diseases" [13] suggests energy selection for treating soft-tissue diseases as low energy (<0.08 mJ/mm^2) and medium energy (0.08–0.14 mJ/mm^2), without specifying number of pulses. Therefore, based on extensive experimental data, this study selected 2000 and 3000 shock waves as treatment pulses per session and investigated four energy levels within the reference range.

In this study, the VAS and CMS scores of patients in each group significantly improved at 1, 2, and 4 weeks after treatment compared to before treatment ($P < 0.05$). Particularly, the CMS scores of Group 3 (7-level, 0.096 mJ/mm^2, 2000 shocks) increased significantly compared to the other groups during the same period indicating that ESWT can significantly alleviate shoulder joint pain, improve joint function, and enhance the quality of life for patients. The treatment with an energy level of 0.096 mJ/mm^2 and 2000 shocks demonstrated the best results. The peak pressure of the shock waves used in this study was low, and the waveform of the output shock waves was stable, uniform, and gentle when applied to patients. This minimizes the risk of local swelling and rupture of small blood vessels, favoring the recovery of soft-tissue damage [14]. Although this study has some limitations, we believe that shock wave therapy for rotator cuff tendinopathy remains the most cost-effective treatment option currently available. In the next steps, we will continue to refine our research, expand the sample size, and extend the follow-up period to obtain more comprehensive data, providing a more reliable and effective treatment method for patients with rotator cuff injuries.

Conclusion

Extracorporeal shock wave therapy for rotator cuff rotator non-calcific tendinopathy can alleviate shoulder joint pain, improve shoulder joint function, and enhance the quality of life with good efficacy. The optimal therapeutic effect was observed at an energy level of 0.096 mJ/mm2 and 2000 shocks.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

Conflicts of Interest: Nil. **Source of Support:** None.

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