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A novel treatment method for ankylosing spondylitis combined with sacroiliac joint bone marrow edema

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Abstract

Objective: To investigate whether high-energy extracorporeal shock wave therapy (ESWT) combined with conventional oral medicine as a potential novel therapeutic approach for the treatment of ankylosing spondylitis (AS)combined with sacroiliac joint bone marrow edema.

Materials & Methods:40 patients were divided into two groups and were treated with or without ESWT in combination with conventional oral medicine. A visual analog scale (VAS) score of spinal pain, as well as indicators of spinal mobility, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Bath Ankylosing Spondylitis Functional Index (BASFI) scores, inflammatory index (C-reactive protein, blood cell sedimentation rate), and other indicators were compared between the two groups. The Spondyloarthritis Research Consortium of Canada (SPARCC) scoring system was used to evaluate pain and structural damage in the sacroiliac joint.

Results:(1) After one month of treatment (T1), VAS, BASDAI, BASFI, and SPARCC scores were lower in both groups than at the start of treatment (T0) ($P < 0.05$), with greater decreases observed in the treatment group ($P < 0.05$). (2) Also, at T1, indicators of spinal mobility for the two groups were improved ($P < 0.05$). (3) ESR and C-reactive protein levels for the two groups decreased significantly at T1 versus T0 ($P < 0.05$).

Conclusion: ESWT combined with oral medication can significantly relieve pain and improve clinical functional symptoms for patients with AS. It can also reduce sacroiliac joint bone marrow edema and control the inflammatory reaction in the sacroiliac joint, which represents a novel, effective, reliable, and safe clinical treatment therapeutic method.

Keywords: Ankylosing spondylitis, Sacroiliac joint, extracorporeal shock wave therapy, oral medicine.

Introduction

Ankylosing spondylitis (AS) is a chronic inflammatory disease that is characterized by changes in the sacroiliac joint that are detected with imaging. [1] The prevalence rate of AS in various countries has been reported to vary from 0.02% to 0.35%,[2] with the disease more commonly affecting young and middle-aged men. The lesions of AS mainly involve the central axis joints, including the spine joints and sacroiliac joints. Disease progression is characterized by pain, stiffness, and decreased activity of the central axis joints after getting up in the morning. Eventually, spinal fusion can occur, accompanied by joint stiffness and hip joint destruction.[3] AS also affects peripheral joints and extraarticular tissues which leads to chronic low back pain and stiffness. Peripheral arthritis, tendon attachment point inflammation, acute uveitis, and intestinal inflammation may also manifest.[4]

The initial symptom primarily reported in cases of AS is lumbosacral pain. Magnetic resonance imaging (MRI) is performed to confirm the diagnosis, and it can detect bone marrow edema(BME) of the sacrum and ilium. Disease progression is marked by bone erosion of the sacroiliac joint, changes in joint space, subchondral sclerosis, and joint stiffness. Greater disease progression significantly and adversely affects the work and life of AS patients, which can create an economic burden for patients and also affect their quality of life.[5]

The etiology of AS remains uncertain, although genetic inheritance is known to play an important role. In particular, the human leukocyte antigen B27 (HLA-B27) gene is strongly associated with the disease[6]. Treatment of AS currently includes non-steroidal anti-inflammatory drugs (NSAIDs), biological agents, and slow acting anti-rheumatic drugs. NSAIDs mainly relieve the pain symptoms of AS patients, yet do not inhibit the progression of axial arthritis and joint edema. NSAIDs also contribute to gastrointestinal reactions. Tumor necrosis

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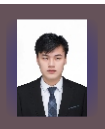
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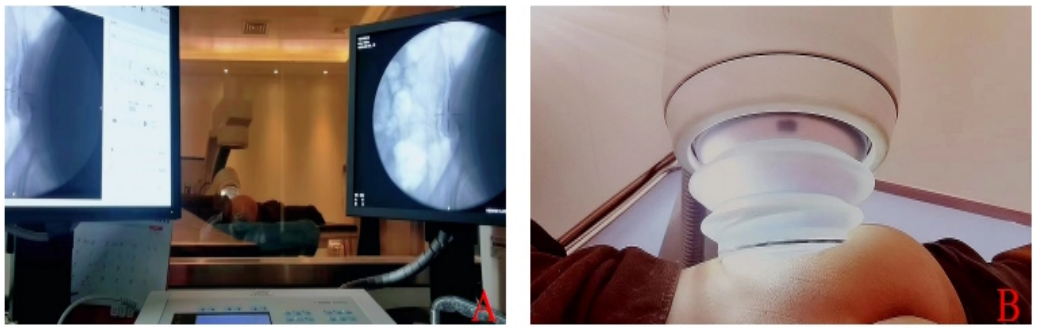

Figure 1: Extracorporeal shock wave photograph with A. Precise localization, B. Real-time monitoring of the impact site.

factor alpha agonist have made obvious effects in the treatment of AS and improved symptoms, although it has not been able to stop progression of AS and it is expensive. Currently, sulfasalazine is an anti-rheumatic drug that is recommended for the treatment of peripheral joints in AS patients.[7] Meanwhile, extracorporeal shock wave therapy (ESWT) is a non-invasive extracorporeal method that is also available.[8] A large number of clinical studies have shown that ESWT has achieved satisfactory clinical results in the treatment of shoulder tendon calcification, fracture nonunion, femoral head necrosis, bone marrow edema (BME) of hip, knee, and other orthopedic diseases.[9-12]

Previous studies of AS have mostly focused on improving patients' clinical symptoms, while important indicators of sacroiliac arthritis and sacroiliac joint edema involved in early axial spinal joints were not examined.[13] There are also relatively few clinical studies on high-energy ESWT for treatment of sacroiliac joint BME and changes in imaging during the early and middle stages of AS. Therefore, the goal of this study was to provide a preliminary evaluation of whether high-energy ESWT combined with oral drugs can improve AS activity, relieve pain, and manifest improvements in sacroiliac joint BME in MRI.

Materials And Methods

Between March 2020 and December 2021, 40 patients diagnosed with AS were recruited to participate in this study. Written informed consent was obtained from each patient and approval for this study was granted by our institutional review board (approval no. 201906).

Patient data

A total of 23 males (57.5%) and 17 females (42.5%) were recruited for this retrospective study (Table 1). The inclusion criterion was patients diagnosed with AS from 18 to 45 years, according to diagnostic criteria revised by the American Rheumatology Society in 1984.[14] Each patient also had MRI performed to demonstrate the presence of BME in the sacroiliac joint. Exclusion criteria included: the presence of other rheumatic immune diseases (e.g., systemic lupus erythematosus, rheumatoid arthritis) in addition to a confirmed diagnosis of AS; patients preparing for pregnancy, pregnant patients, and lactating patients; patients with severe diseases involving heart, brain, lung, liver, or kidney, as well as other basic diseases; patients with a history of an abnormal hematopoietic system, impaired blood coagulation function, or malignant tumor; severe osteoporosis, patients aged < 18 y and > 45 y; and patients with severe mental disorders who were unable to participate. The 40 patients were divided into a treatment group (n = 20) and a control group (n = 20).

Therapeutic method

Both the control group and the treatment group were instructed to take an Imrecoxib tablet(0.1 g, bid) and a Sulfasalazine enteric-coated tablet (1 g, bid), in the morning and the evening. In addition, patients in the treatment group received high-energy ESWT from a shock wave electromagnetic source (Dornier Compact Delta II, Dornier MedTech GmbH, Wessling, Germany). This source was fitted with C-arm fluoroscopy device to achieve precise localization, real-time monitoring of the impact site, and recorded the impact energy value during the treatment process (Figures 1). The specific treatment plan was as follows: Prior to treatment, the patient underwent MRI of the sacroiliac joint. This imaging helped to accurately locate the sacroiliac joint under the C-arm fluoroscopy when the patient lied prone on the treatment bed. The site of BME was marked on the patient's surface skin. A coupling agent was applied between the skin of the treatment site and the treatment balloon as the energy transfer medium. A close fit between the balloon surface and the skin was observed under the display to eliminate a gap and avoid energy loss. At each treatment session, 4 to 5 treatment points were selected and each treatment point was impacted 500 shocks, and a total of 2000 to 2500 shots were applied with a flux energy density of 0.50mJ/mm2. A treatment cycle included one treatment every 7 days and a total of four cycles were completed.

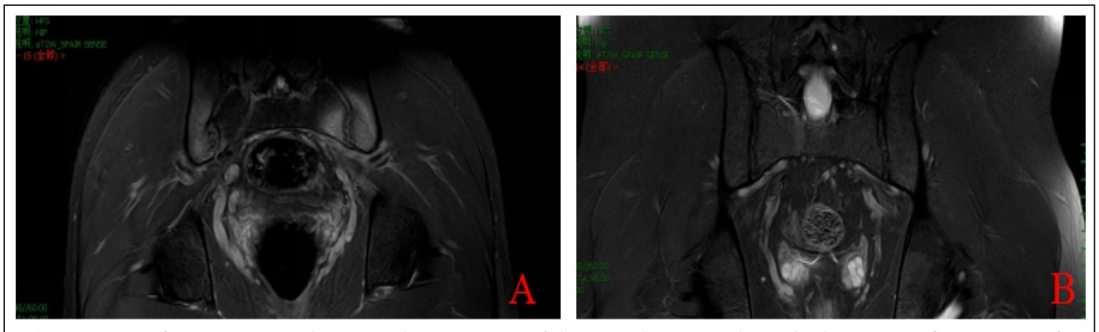

Figure 2: A: Before treatment, the coronal MRI T2WI of the sacroiliac joint showed a large area of BME. B: After treatment, the coronal MRI T2WI of the sacroiliac joint showed reduction in the BME basically, and only a small amount of the right sacroiliac joint hyperintense signal.

Outcome parameters

(1) Pain index: Subjective

Table 1. Pre-treatment (T0) patient data for the control and treatment groups.

Group	N	Gender (M/F)	Mean age ± SD (months)	Mean course of disease (months)	HLA-B27 positive cases
Control	20-Jan	13 / 7	30.53 ± 8.91	18.53 ± 7.41	19-Jan
Treatment	20	45634	31.73 ± 6.95	20.60 ± 7.58	20
x^2 / t		0.045	-0.545	-0.924	0.823
P		0.53	0.59	0.37	0.21

Table 2. Comparison of VAS, BASFI, BASDAI, and SPARCC scores between the control and treatment groups.

Group	N	T0 vs. T1	VAS	BASFI	BASDAI	SPARCC
Control	20	T0	8.14 ± 1.32	6.41 ± 1.13	5.39 ± 1.31	32.45 ± 9.58
		T1	5.26 ± 1.12*	2.44 ± 0.68*	2.34 ± 0.57*	15.00 ± 5.73*
Treatment	20	T0	8.06 ± 1.41	6.31 ± 1.33	5.26 ± 1.51	33.16 ± 8.61
		T1	4.22 ± 1.21*#	2.01 ± 1.57*#	1.93 ± 0.48*#	11.47 ± 5.35*#

pain and discomfort felt in the sacroiliac joint by each patient was measured using a visual analog scale (VAS). (2) Spinal range of motion was examined according to: Schober test, scoliosis, the distance between patients' fingers and ground, Occiput to wall distance, and thoracic range of motion. (3) Degree of disease activity was assessed based on Bath Ankylosing Spondylitis Function Index (BASFI)[15] and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)[16] scores. Both indices are scored using a scale from 0 to 10, with higher scores indicating worse symptoms.(4) Laboratory examination: Inflammatory indicators, including C-reactive protein and erythrocyte sedimentation rate (ESR), were detected in serum samples that were collected on an empty stomach from patients in the morning and then analyzed at our hospital's laboratory. (5) Imaging observation: MRI scanning was performed by radiologists at the hospital. One month after completion of treatment, the scoring system of the Spondyloarthritis Research Consortium of Canada (SPARCC) was applied by two imaging professionals who were blinded to the results to quantitatively analyze and evaluate the degree of acute inflammation observed in the sacroiliac joint.[17] All of the outcome parameters described above were evaluated before (T0) and 1-month after (T1) treatment for both the control and treatment groups.

Statistical analysis

Clinical data were analyzed with SPSS19.0 statistical software (Chicago, IL, USA). Measured data are expressed as the mean ± standard deviation (SD). The Chi-square test was applied to count data. The Independent sample t-test was used to compare age, course of disease, clinical scores, and laboratory indexes of the two groups before and after treatment. A probability (P) value less than 0.05 was considered statistically significant.

Results

All of the recruited patients successfully completed the treatment and follow-up period for their assigned group. General data for the two groups collected before treatment (T0) are presented in Table 1. None of the patients in either group manifested adverse reactions during treatment or follow-up and all safety indicators were normal.

One month after treatment (T1), the VAS, BASFI, BASDAI, and SPARCC scores of the treatment and control groups significantly improved compared with their respective T0 values (P< 0.05). Furthermore, all four scores for the treatment group at T1 were significantly improved compared to the same categories in the control group at T1 (P < 0.05) (Table 2).

Compared with before treatment in this group,*P<0 05.Comparison between the treatment group and the control group,#P<0 05.

Physical indicators of spinal mobility were also examined before and after treatment for both groups. Occiput to wall distance and finger ground distance for both groups were shorter at T1 compared with T0. Scoliosis, thoracic range of motion, and Schober test scores were also improved at T1 compared with T0. Moreover, all physical indicators of spinal mobility for the treatment group at T1 were superior to those of the control group at T1, and the differences were significant (P < 0.05) (Table 3).

ESR and C-reactive protein levels in the control and treatment groups decreased significantly from T0 to T1 in each group (P < 0.05). However, the differences between the T1 and T0 values for each group did not significantly differ between the two groups (P > 0.05) (Table 4).

Compared with before treatment in this group,*P<0 05.

A representative case from the treatment group, a 24-year-old female patient with AS and sacroiliac joint bone marrow edema, is presented in Figure 2.

Discussion

AS is a progressive inflammatory disease with a slow and lengthy onset that is not often marked by noticeable symptoms. To date, the etiology and pathogenesis of AS remain

Table 3. Comparison of physical signs of spinal mobility indicators between the control and treatment groups.

Group	N	T0 vs. T1	Schober test score	Scoliosis (°)	Distance between fingers and ground (cm)	Distance between occipital wall (cm)	Thoracic range of motion (cm)
Control	20	T0	4.12 ± 1.44	37.94 ± 11.32	24.60 ± 4.86	4.32 ± 1.19	3.91 ± 0.54
		T1	5.72 ± 2.25*	45.12 ± 12.54*	19.60 ± 5.63*	3.48 ± 1.12*	4.27 ± 1.35*
Treatment	20	T0	4.54 ± 1.56	36.82 ± 10.27	26.33 ± 1.51	4.24 ± 1.27	3.89 ± 0.46
		T1	6.25 ± 2.32*	48.99 ± 14.84*#	17.7 ± 5.91*#	2.74 ± 1.11*#	4.45 ± 1.26*#

Table 4. Comparison of ESR and CRP between the control and treatment groups.

Group	N	T0 vs. T1	ESR (mm/h)	CRP (mg/L)
Control	20	T0	49.54 ± 4.32	26.32 ± 3.07
		T1	17.23 ± 4.44*	13.45 ± 5.53*
Treatment	20	T0	51.17 ± 2.64	27.58 ± 3.36
		T1	16.23 ± 3.38*	12.13 ± 4.52*

unclear. However, it is generally believed that genetic, immune, cell signal transduction, natural environment, and other factors all contribute.[18] Approximately 90% of AS patients first manifest inflammatory edema of the sacroiliac joint, predominantly on the anterior lower 2/3 iliac side.[19] Furthermore, inflammation associated with AS is generally present throughout the entire disease course. Consequently, strict control of inflammation activity is an important step in reducing joint stiffness and maintaining function.[20] It has been demonstrated that MRI is the imaging method that is most sensitive to the detection of bone marrow edema in the sacroiliac joint and spine compared to other clinical indicators.[21] Therefore, it is necessary to perform a MRI examination of the sacroiliac joint when AS patients are first diagnosed in order to clarify the extent of inflammatory edema present. Then, active and effective intervention measures can be implemented to control inflammation and reduce or relieve clinical pain symptoms, while also improving and maintaining normal posture and optimal function of the limbs. Cumulatively, this will improve patient quality of life, which can have important clinical significance.[22]

NSAIDs are internationally recognized as the first-line treatment drugs for AS. NSAIDs effectively control AS inflammation, improve patients' back pain and morning stiffness, reduce joint swelling and pain, and increase joint range of motion.[23] Sulfasalazine is also widely used in the clinical treatment of AS. As a sulfonamides antibacterial agent, it mediates three mechanisms of action: antibacterial, anti-rheumatism, and immunosuppression. With an ability to reduce the antibody immune response in the body of AS patients and regulate their immune system, sulfasalazine is an important agent.[24] However, while a combination of NSAIDs and sufasalazine has achieved a certain degree of clinical efficacy in the treatment of AS, this regimen does not control the disease. Long-term adverse reactions to these drugs have also been reported.[25] Therefore, a safer and more effective treatment regimen is needed to improve clinical efficacy for AS patients.

In recent years, ESWT has been widely used in clinical practice because of its safe and non-invasive effects, as well as the minimal complications associated with its use.[26] Relevant studies have confirmed that ESWT can reduce inflammatory swelling and the pain associated with lower limb tendon diseases.[27]At present, the specific mechanism(s) by which ESWT treats AS remain unclear. Mariotto[28] has hypothesized that the anti-inflammatory mechanism of ESWT increases the activity of endothelial nitric oxide synthase through tyrosine phosphorylation, and production of nitrogen monoxide achieves an anti-inflammatory effect. Ko[29] has also hypothesized that ESWT improves the extracorporeal pain domain to relieve pain. Meanwhile, others have hypothesized that ESWT can reduce NF-κB activation of and NF-κB-dependent gene expression that mediates an anti-inflammatory role.[30] Relevant animal experiments have shown that[31] ESWT significantly reduced IL-1α, IL-4, IL-6 and other proinflammatory cytokines in mice on the sixth day after treatment. Wang[32] further confirmed that ESWT can release adhesive tissue, promote angiogenesis, improve microcirculation, reduce inflammatory reaction, promote new bone formation, and enhance cell metabolism through physical, cavitation, and tension effects. Based on these previous insights, we hypothesize that the ability of ESWT to improve pain and function in AS patients is related to its capacity to mediate an analgesic effect, inhibit an inflammatory reaction, and improve circulation to induce relaxation.

In the present study, VAS and BASFI scores in the two groups were significantly improved after treatment compared with before treatment ($P < 0.05$). In addition, the scores in the treatment group were superior to those of the control group, suggesting that ESWT can mediate an analgesic role in the treatment of AS. The BASDAI scores, as well as the five physical signs of spinal mobility indicators (Occiput to wall distance and finger ground distance were shorter than those before treatment, spinal scoliosis, thoracic range of motion, Schober test) of the two groups of patients also improved after treatment ($P<0.05$). Taken together, these results indicate that high-energy ESWT combined with drugs can improve joint function and range of motion in AS patients, which can help maintain normal physiological activity of the spine. To evaluate the degree of BME of the spine in the present study, SPARCC scores were used as the main outcome indicator. After one month of ESWT treatment, the T2WI high signal area of transverse and coronal MRI of the sacroiliac joint was observed to decrease. BME of the sacroiliac joint was also significantly reduced. In both groups, the SPARCC scores decreased after treatment, with the treatment group having lower SPARCC scores than the control group. ESR and C-reactive protein levels in the two groups also exhibited statistically significant improvement after treatment ($P<0.05$). Overall, these results indicate that a combination of ESWT is more effective in improving BME in patients experiencing early and middle stages of AS, and also exhibits better clinical efficacy in controlling inflammatory reactions during these same stages.

Limitations of this study

While demonstrating satisfactory clinical efficacy, this study also has limitations. First, this study involved a single center and the follow-up time was relatively short. The sample size of the patients included in the study was also relatively limited. Consequently, a multi-center study needs to be conducted in order to achieve a larger sample size and a longer duration of follow-up. Second, the mechanism(s) mediating the effects of ESWT for AS and acute inflammation remain unclear. Thus, further research is needed.

Conclusion

Our results demonstrate that ESWT combined with oral medicine significantly

relieved pain and improved clinical functional symptoms among the AS patients examined. In addition, BME of sacroiliac joint was reduced, the inflammatory reaction of the sacroiliac joint was controlled, and disease progression appeared to be delayed based on imaging results. Thus, high-energy ESWT combined with oral medicine appears to be a represents a novel, effective, reliable, and safe clinical treatment therapeutic method for AS that warrants further study.

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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