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CLINICAL PHARMACY

Clinical analysis of the efficacy of thalidomide combined with finger pointing in the treatment of ankylosing spondylitis

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[Abstract] **Objective** This study aims to investigate the different treatment protocols for ankylosing spondylitis (AS) in the clinic. In this paper, finger point therapy and thalidomide were proposed to be used in the treatment of the disease, and the effects were evaluated. **Methods** Sixty-eight patients with AS were randomly divided into two groups: the control group and the treatment group, with 34 cases in each group. The two groups were given different medication regimens to compare the differences in symptoms and signs and efficacy after different regimens were implemented. **Results** After treatment, the experimental outcomes of the Schober test, occipital wall distance, finger-ground test, blood sedimentation, C-reactive protein, IL-6, TNF-α, and ASDAS index level in the treatment group were significantly different from those in the control group (P<0.05), and the treatment group's overall effective rate was 100% significantly higher than that of the control group (χ^2=7.988, P< 0.05). **Conclusion** The symptoms and signs of patients with AS could be significantly improved by thalidomide with finger point therapy.

[Key words] Ankylosing spondylitis; Finger acupuncture; Jiaji point; Thalidomide

1 Introduction

Ankylosing spondylitis (AS) mostly occurs in young and middle-aged men and is an inflammatory disease that primarily affects joints, such as the sacroiliac and spine[1]. Pain and stiffness in the lower back or buttocks are common symptoms. As the disease progresses, it will cause bone rigidity and joint fusion, eventually leading to deformity, disability, and even loss of independent living ability of the patient's spine[2]. The burden caused by the disease will increase with the extension of the disease course, and AS will impose a huge burden on patients and society. At present, AS has no radical plan and can only treat the symptoms of pain and stiffness with drugs. Traditional antirheumatic drugs, such as sulfasalazine, methotrexate, and thalidomide, which are commonly used in clinic, can change or inhibit inflammation of the spine and attachment points. Traditional Chinese medicine (TCM) has a distinct effect in the treatment of AS; however, both TCM and Western medicine have shortcomings in the treatment of AS[3]. When compared with single

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drug therapy, finger acupuncture plus Western medicine has the advantages of rapid symptom control, stable curative effect, less toxic and side effects, patient acceptability, and simple operation. Finger acupuncture works by relaxing tendons and activating collaterals, dredging collaterals and relieving pain, tonifying kidneys and strengthening bones, treating both symptoms and root causes, attacking and reinforcing simultaneously, filling marrow and nourishing bones, and smoothing meridians. Finger acupuncture technology is more suitable for symptomatic treatment. Combining appropriate acupoints with the specific symptoms and characteristics of patients can improve therapeutic effect and is suitable for popularization and application in clinical treatment[4]. In light of this, this paper reports the application effect of thalidomide combined with finger acupoints for treating AS patients on the basis of routine treatment to further examine the implementation effect of Western medicine combined with acupoints along meridians.

2 Clinical data

2.1 General information

From January 2018 to January 2022, all 68 patients were patients with AS admitted to the Department of Rheumatology, No.923 Hospital of the People's Liberation Army. The selected patients were diagnosed by radiology, and their blood routine and routine biochemical examination of the liver and kidney were performed before they were selected. The selected age was 13–50 years old. The patients were randomly divided into two groups, with 34 cases in each group. Basic data of the treatment group were as follows: 32 males and two females aged 16 to 55 yr; the course of disease was 0.3–25 yr. The control group consisted of 33 males and one female. The age ranged from 15 to 54 yr, with an average of 21.87 ± 1.71 yr. The course of disease is 0.4–20 yr. According to the statistics, there was no statistically significant difference in the basic data between the experimental and control groups (P>0.05).

2.2 Diagnostic criteria

This study was approved by the Ethics Committee of No.923 Hospital of PLA (Subject number: Z20170061). All of the patients signed the informed consent form.

The following diagnostic criteria are consistent with the 2015 American Rheumatology Association/European Anti-Rheumatology Union Gout Classification Criterion[5]: (1) Low back pain lasts at least 3 months and improves after exercise. (2) The lumbar spine's anteroposterior and lateral flexion is severely limited. (3) The range of thoracic expansion is smaller than the reference range of healthy people of the same age. (4) Bilateral sacroiliac joints are classified as Grade II – IV, whereas one side is classified as Grade III – IV. (5) Item 4 can be diagnosed when combined with any of the first three items.

2.3 Inclusion criteria

The following are the inclusion criteria: (1) The age range is 13–50 years old. (2) The AS diagnostic criteria should be met. (3) The disease is currently in an acute active stage. (4) The participants were informed and required to sign a consent form.

2.4 Exclusion criteria

The following are the exclusion criteria: (1) Patients with severe organ dysfunction. (2) Patients with severe spine deformity. (3) Patients who quit the researcher halfway or patients who drop out of the study halfway.

3 Treatment methods

3.1 Groups divided

3.1.1 Control group

Thalidomide tablets (Changzhou Pharmaceutical

Co., Ltd., SFDA approval number H32026129; initial dose, 50 mg/night, maintained at 50 mg/night every 10 days) and celecoxib capsules (Zhengda Qingjiang Co., Ltd., National Medicine Zhunzi H20193414; usage: 0.2 g orally once a day).

3.1.2 Treatment group

Finger acupoints are added on the basis of treatment. Methods: once a day for 20 min, 12 days of treatment, and four continuous treatments. Manipulation: Push the palm from the thoracic vertebra to the coccygeal vertebra 10 times, then press the thumb and abdomen along the Du Meridian and Jiaji points of the spine, and repeatedly press the spinous process and Jiaji points of the cervical, thoracic, lumbar, and coccygeal vertebrae from top to bottom.

3.2 Observation indicators

3.2.1 Spinal mobility

The individual's spinal mobility was assessed before and after treatment, with detection indices including the distance between the ground and the occipital wall and the Schober test.

3.2.2 Inflammation index

The erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), interleukin-6 (IL-6), and tumor necrosis factor α (TNF-α) were measured before and after treatment, and the disease activity score (ASDAS) of ankylosing spondylitis was evaluated.

3.2.3 ASDAS

ASDAS–CRP=0.12 times; back pain score + 0.06 times; morning stiffness time score + 0.11 times; overall score + 0.07 times; peripheral joint pain/tenderness score+0.58 times; (CRP + 1) natural logarithm. ASDAS <1.3 indicates remission, 1.3–2.1 indicates low activity, 2.1–3.5 indicates high activity, and >3.5 indicates extremely high activity. A high score indicates that the higher the disease activity, the more serious the disease is.

3.4 Evaluation of curative effect

According to the seminar summary on clinical and epidemiological research of AS[6], the curative effect was evaluated as follows. Marked effect: symptoms disappeared completely, and ESR and CRP indices were normal; effective: symptoms improved, and ESR and CRP indices improved by at least 50%; invalid: none of the above two standards are met. The total effective rate is the sum of marked effect an effective rate.

3.5 Statistical processing

The statistical data of this paper were analyzed using SPSS 23.0 software. The measurement data and counting data were tested using t test and χ^2 test, respectively, and $P<0.05$ means and the results between groups were statistically significant.

4 Treatment results

4.1 Symptom improvement

The curative effect of the treatment group was significantly better than the control group ($P<0.05$) (Table 1).

4.2 Clinical indications improvement

Analyze the spinal mobility and inflammatory indices of patients with AS before and after treatment in the two group. There was a significant difference between the two groups before and after treatment ($P<0.05$) in the schober test results, occipital distance, finger test, ESR, CRP, IL-6, TNF-α, ASDAS respectively (Table 2).

5 Discussion

Ankylosing spondylitis is a chronic progressive disease that mainly affects the sacroiliac joint, spinous process, and peripheral joint of soft tissue accumulation near spine and may be accompanied

Table 1 Comparison of clinical symptom improvement between treatment and control groups

Groups	Case no.	Markedly effective	Effective	Ineffective	Total effective rate (%)
Control group	34	15	13	6	82
Treatment group	34	28	6	0	100

Note: Treatment groups *vs* control group, $^{*}P<0.05$.

Table 2 Comparison of clinical indications between the treatment and control groups before and after treatment

Observation index	Control group		Treatment group	
	Before treatment	After treatment	Before treatment	After treatment
Schober test (cm)	3.47±0.13	3.37±0.13*	3.61±0.18	3.94±0.14*
Occipital wall distance (cm)	3.08±0.024	3.81±0.26*	1.95±0.34	1.69±0.39*
Finger-to-ground experiment (cm)	18.37±1.66	20.82±1.61*	18.32±1.85	15.75±1.72*
Erythrocyte sedimentation rate (mm/h)	25.70±3.32	20.58±2.84*	24.63±2.95	20.14±2.65*
CRP (mg/L)	17.50±3.54	14.23±1.71*	19.68±1.68	13.67±1.38*
IL-6 (ng/mL)	21.38±3.50	16.34±2.35*	21.83±2.50	14.30±1.28*
TNF-α (pg/mL)	27.64±3.64	16.51±2.15*	34.32±5.19	22.07±3.20*
ASDAS (score)	2.79±0.10	2.04±0.07*	2.79±0.12	1.59±0.07*

Note: Treatment groups *vs* control group, $^{*}P<0.05$.

by extra-articular manifestations, which may lead to severe spinal deformity and ankylosis. There is still no radical cure for AS. AS should be treated with long-term follow-up under the guidance of specialists. The treatment plan includes comprehensive treatment of non-drugs, drugs, and surgery. The goal is to relieve pain and stiffness, control or alleviate inflammation, maintain good posture, prevent spinal or joint deformation, and correct deformed joints when necessary to improve patients' quality of life.

Drug therapy is mainly based on non-steroidal anti-inflammatory drugs, such as thalidomide, sulfasalazine, methotrexate, and biological agents. The purpose of the drug is to reduce inflammation and symptoms in patients, prevent progressive changes in the body, and protect patients' normal physical and social functions, allowing them to return to normal life and work. Thalidomide can clearly alleviate clinical symptoms, ESR, and CRP and promote the degradation of TNF-α messenger. It has two-way effects of immunosuppression and immunostimulation and inhibits monocytes from producing TNF-α and IL-6[7-8]. The common side effects of thalidomide are drowsiness, thirst, constipation, dizziness, a decrease in blood cells, an increase in liver enzymes, hematuria under a microscope, and a tingling sensation at the fingertips. Blood and urine routines were examined every week at the start of medication, and liver and kidney functions were checked every 2–4 weeks. Patients who have been taking drugs for a long time should undergo a regular nervous system examination to detect possible peripheral neuritis in time. Feng et al.[9] conducted an open study on the effect of thalidomide on patients with AS, which showed that the level of TNF-α in patients decreased significantly after treatment and 80% of patients' symptoms improved. Long-term use of thalidomide could improve their condition. Jing et al.[10] research results showed that thalidomide had a good therapeutic effect on refractory AS, improving body function while also regulating the level of serum immune factors, protecting joint and tendon tissues from being affected, and reducing the level of inflammatory factors while improving the level of immune indicators. In the study of Lihua[11], thalidomide combined with SASP improved the symptoms and signs of patients with AS while effectively inhibiting disease deterioration and development. Of course, not all patients with AS have an obvious

therapeutic effect on thalidomide, and some patients have a poor response or obvious adverse reactions to this drug due to physical factors, so the therapeutic regimen must be adjusted according to the needs of disease treatment, and it should be used in combination.

Ankylosing spondylitis is classified as a "big fistula" in TCM. According to the theory of TCM, the main cause is kidney deficiency, and the basic pathological mechanism is deficiency of natural endowment, vegetarian body weakness, and liver blood deficiency of kidney essence, which leads to bone damage. Clinical symptoms include spinal rigidity, deformity, serious obstacle to activity, dull complexion, and emaciation. Its nature is deficiency in essence and excess in substance, emptiness in the kidney governor, and wind–cold dampness. Therefore, the main methods of treatment are tonifying the kidney and strengthening supervision, expelling wind and cold, promoting blood circulation, and dredging collaterals. External treatment with TCM provides a unique effect in the treatment of AS. Every therapy has its own advantages and disadvantages. Combining Chinese and Western medicine can improve efficiency and reduce toxicity, and acupoints along the meridian can activate qi and blood circulation, relax tendons and activate meridians, tonify liver and kidney, strengthen bones and muscles, activate yang, dispel wind and dampness, and stop arthralgia[12]. It can play the role of tonifying the kidney and dredging governor and can be used in AS according to the cause. Acupuncture along the meridians combined with thalidomide for the treatment of AS can improve efficacy and reduce the toxicity. The disadvantages in the ointment of this treatment scheme include that the treatment effect will be affected by doctors' skill and strength and the patients' compliance. In general, the implementation of this scheme is beneficial to the overall treatment of AS, and it has different curative effects for AS at different stages, with the best effect in the early stage, the second in the middle stage, and the worst in the late stage. Acupuncture combined with thalidomide can play a synergistic role in the treatment of AS, relieving pain, improving spinal mobility, controlling the disease, and maintaining the disease in a low activity state for a long time, and is worthy of widespread clinical use.

6 Conflicts of interest

These authors have no conflicts of interest to declare.

7 Author contributions

QIN Liangyi: data curation, writing–original draft preparation. LAI Jing: writing–reviewing and editing.

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